CLINICAL EVALUATION OF SIDDHA DRUG MEGA RAJANGA KIRUTHAM IN THE TREATMENT OF VELLAI NOI (LEUCORRHOEA)

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "CLINICAL EVALUATION OF SIDDHA DRUG "**MEGA RAJANGA KIRTHAM** IN THE TREATMENT OF **VELLAI NOI (LEUCORRHOEA)"** Guidance of **Prof. Dr. K. Manickavasakam, M.D(s)** in Department of Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: **Signature of candidate**

Place: Chennai-47 **(Dr.S. SANTHANAKITTU)**

CERTIFICATE

This is to certify that this dissertation work on **"CLINICAL EVALUATION OF SIDDHA DRUG MEGA RAJANGA KIRTHAM IN THE TREATMENT OF VELLAI NOI (LEUCORRHOEA)"** has been carried out by Dr.S. SANTHANAKITTU Reg No.321411208 during the year 2014-2017 in the Department of Maruthuvam, National Institute of Siddha, Tambaram sanatorium, Chennai 47 under my guidance and supervision in partial fulfilment of regulation laid by The TamilnaduDr.M.G.R Medical University, Chennai for the Final M.D (Siddha), Branch I- MARUTHUVAM Examination to be held in OCTOBER – 2017. This dissertation work is not reprinted or reproduced from any of the previous dissertation work.

PROF. Dr. K. Manickavasakam, M.D(s),

Head of the Department and Guide

Department of Maruthuvm.

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INTRODUCTION

Siddha system of medicine is an ancient, and holistic medical system among all system of medicine in the world, it was founded by siddhars who were spiritual and efficient scientists. The term siddha comes from the word siddhi which means attainment of perfection.

Medicine is all about preventing and treating ailments thus postponing death. An interesting aspect of siddha system of medicine is its view about death. Thirumoolar defines the ailments of the body and mind as diseases. In the same breath he defines death as disease and hence could be prevented.

மறுப்பது உடல் நோய் மருந்தெனலாகும்
மறுப்பது உளநோய் மருந்தெனச்சாலும்
மறுப்பது இனி நோய் வாராதிருக்க
மறுப்பது சாவையும் மருந்தெனலாமே

- திருமூலர்

One that cures physical ailment is medicine
One that cures psychological ailment is medicine
One that prevents ailment is medicine and
One that bestows immortality is medicine

- Thirumoolar

A perfect health is the first step towards greater intellectual pursuits. According to Siddhars it is achieved by adhering to a very strict personal discipline.

Siddha system is the true knowledge of natural laws and remains forever.

The human body is made up of five elements of nature namely Mann (Earth), Neer (water), Thee (Fire), Vayu (air), and Aagasam (Space).

The physiological function of the body is mediated by three vital humours namely Vatham, Pitham, Kabam. According to the siddha system of medicine, diet and life style play a major role not only in health but also in curing diseases.

மிகினும் குறையினும் நோய் செய்யும் நூலோர்
வளிமுதலா எண்ணிய மூன்று. -குறள் 941

Excess or deficit of any action which produces more or less of the three humours beginning with Vali (wind) is reckoned by the authors of medical science to cause disease.

When the normal equilibrium of 3 humours is disturbed disease is caused. The factors which affect this equilibrium are environment, climatic conditions, diet, physical activities and emotions.

Vellai noi (leucorrhoea) is one, which affects the women commonly and frequently. The natural vaginal discharge may vary considerably, especially under differing hormonal influences such as puberty, pregnancy or prescribed contraception. A sudden or recent change in discharge, especially if associated with alteration of color and smell, or vulval itch/ irritation is more likely to indicate an infective cause than gradual or long- standing change.

Local epidemiology is particularly important when assessing possible causes. In the UK, most cases of vaginal discharge are not sexually transmitted, being due to either candidal infection or bacterial vaginosis. World-wide, the most common treatable Sexually Transmitted Infection causing vaginal discharge is trichomoniasis; other possibilities include gonorrhoea and Chlamydia. Herpes Simplex Virus may cause increased discharge, although vulval pain and dysuria are usually predominant symptoms. Non-infective causes include retained tampons, malignancy and/ or fistulae.

Trichomoniasis is a cosmopolitan disease usually transmitted by sexual intercourse. It is estimated that 3 million women in the United States and 180 million worldwide acquire this disease annually, and 25% of sexually partners are also parasitized at least transiently.

Trichomoniasis tends to cause a profuse yellow or green discharge and is usually associated with significant vulvo-vaginal inflammation. Diagnosis is made by observing motile flagellate protozoa on wet mount microscopy slide of vaginal material.

Vaginitis is the second most common gynaecological problem after menstrual disorders. It is a physical, social, emotional and economical problem. It is observed that 15-20% of vaginal infection is due to Trichomonas vaginalis (a protozoon).

Women must be educated to lead a healthy life. Then only they can make their family healthy.

Women in reproductive age group and even young girls are commonly affected by vellai noi.

As per siddha literature Agasthiyar gunvagadam (pgno; 269, poem 1081) Vellai noi (syn; Piramiyam, Piramegam) has been enumerated as per the following symptoms lower abdominal pain, purulent white discharge can be correlated with LEUCORRHOEA in modern science.

Vaginal Infection is more common in women of childbearing age & in older women (post menopausal period). The factors like increasing age, illiteracy, low socioeconomic status, high parity, induced abortion & place of delivery are all contributing factors for occurrence of vaginal discharge.

Siddha formulations not only treat this disease but also strengthen the entire female genital tract. We are receiving more number of Vellai noi cases in our OPD which is the driving force behind to select this topic for my dissertation study.

As preparation of the trial drug is cost effective efficacious & easily available. I have chosen Mega rajanga kirutham for the treatment of "VELLAI NOI (LEUCORRHOEA)''.The below ingredients of MEGA RAJANGA KIRUTHAM(Internal), Athimathuram (Root of *Glycyrrhiza glabra* Linn),Naval pattai (stem bark of *Lannea coromandelica* Houtt), Karumbu rasam (Juice of *Saccharam indicum* Linn),Nellikai charu (Juice of *Embelica officinalis* Linn),Elumichai rasam (Juice of *Citrus lemon* Linn),Gingely oil, Ealam (Seed of *Elettaria cardamomum* Maton),Kirambu (Flower bud of *Syzygium aromaticum* Linn),Sathikai (Seed of *Myristica fragrans* Houtt),Citrarathai (Rhizome of *Alpinia officinarum* Linn), Nilapanai kizhangu(Root tuber of *Curculigo orchioides* Goertn), are found to cure Vellai noi as per Gunapadam Mooligai vaguppu. No clinical documentation on Mega rajanga kirutham in the treatment of Vellai noi has been found yet. So there is a need to evaluate the therapeutic efficacy of this classical Siddha formulation **"MEGA RAJANGA KIRUTHAM"** mentioned in Sigicha rathna deepam for scientific validation.

AIM & OBJECTIVES

AIM

To find out the efficacy of Mega rajanga kirutham in the treatment of vellai noi.

OBJECTIVES

PRIMARY OBJECTIVE:

To evaluate the therapeutic efficacy of **MEGA RAJANGA KIRUTHAM** in the treatment of **VELLAI NOI (LEUCORRHOEA)** by using Wet test.

SECONDARY OBJECTIVE:

- Reduction of clinical symptoms
- To study the cofactors related to the disease (i.e., age, socioeconomic status)
- To prepare the trial drug as per SOP drug preparation.
- To evaluate the **anti inflammatory** activity.
- To evaluate the **anti microbial** activity.
- To evaluate the **physico chemical** analysis.
- To evaluate the **antioxidant** activity.

REVIEW OF LITERATURE

SIDDHA ASPECTS

VELLAI NOI

SYNONYMS:

Pramiyam, pramegam, ozhukku vellai, Vettai noi, ven theettu.

DEFINITION:

"சொல்லுகின்ற வேளை தன்னிலடி வயிற்றில் தானும்
செயலாக வேதனையை யுண்டாக்கும் பாரு
மகத்தான ஆணுக்கு நீர்தாரையினின்றும்
மகத்தான பெண்ணுக்கு ஜனன இந்திரியந் தன்னில்
தொல்லுலகில் சீப்போல வெளுத்த நீராய்
தொப்பனவே வடிகின்ற மேக நீருக்கு
அல்லல்செய்யும் வெள்ளையென்றும் சொல்வார் மேலோர்"

- Agasthiyar Gunavagadam

Lower abdominal pain, Pus like pale watery discharge from vaginal orifice in female & from urethral orifice in male is called as “Meganeer” or Leucorrhoea or Vellai noi.

AETIOLLOGY:

I. ACCORDING TO AGASTHIYAR GUNAVAGADAM

"கேளடா பிரமேக உற்பத்தி தன்னை
கெணிதமுடன் சொல்லுகின்றேன் நன்றாய் கேளு
நானடா ஸ்த்ரீபோகம் அதிகரித்தாலும்
நன்மையுடன் மோகமுடன் பட்டினியாலும்
வாளடா ஸ்தம்பனங்கள் செய்வதாலும்
பாழடா அதிகமாய் புசிப்பதாலே
பாங்கான பிரமேகந் தோணும் பாரே"

1) Repeated sexual act
2) Lustfulness with starvation
3) Restraining the ejaculation of semen during sexual intercourse
4) High intake of salty, spicy &astringent foods.

II. ACCORDING TO THIRUMOOLAR KARUKKADAI VAITHYAM 600

" அன்னம் பிறந்தது அனைத்து விதையிலும்
மன்னிய வெட்டை மகாசீதம் இரண்டினால்
பன்னி அறிந்திதைப் பார்பார் பெரியோர்கள்
கன்னி மயக்கத்தால் கண்டிடும் மேகமே"

"மேகம் பிறந்த விதந் சொன்னா ரெந்நந்தி
ஆம்மிளத்தைப் பருவமதில் மோகித்தும்
போகந்தினஞ் செய்யிற்புகழ் மந்தத்தே கூடில்
வாகப் பசியால் வழங்கஞ் சையோகமே"

"சையோகம் செய்யத் தனித்த சுழியோடும்
ஐயா அமிர்தம் அடக்கிக் கனலேறும்
மெய்யாக விந்துவிழப் புண்ணாகும்
மையான மேகம் வளருங் கிரந்தியே"

III. ACCORDING TO AGASTHYAR VAITHYA KAAVIYAM 1500:

"கேளப்பா வெட்டை பித்தம் கெடியான வாதம் வாய்வு
வாளப்பா வையஞ்சீதம் வளர்ந்திடும் அன்னத்தாலே
பாளப்பா அன்னந்தானும் பகையுடன் பழியும் கொள்ளும்
வேளப்பா அன்னத்தாலே மேகங்கள் பிறப்பை கேளு"-Poem35

மேக உற்பத்தி:

"மேகங்கள் பிறந்து நின்ற விதங்களை விளம்பக் கேளு
ஆகங்கள் இகழ்ந்தபோது அப்பனே தினமும் சென்ற
போகங்கள் செய்யும் போதும் புகழ்மந்தம் கூட்டும்போதும்
பாகங்கள் பசியனூடும் பருகுஞ் சையோகந்தானே

சையோகஞ் செய்யும் போதும் தனிநின்ற சுழியேயோடு

மையவோ அமுர்தந்தன்னை அடக்கியே அனல்தான்

மெய்யடா விந்துகாணில் விழவிழப் புண்ணுந்தானு

மையடா மேகத்தாலே வளர்ந்தது கிரந்திபாரே" – Poem 36

Insulting and reticulating the sacred books, Excessive sexual act, having sex during indigestion & hungry and suppressing the ejaculating of semen during sexual act cause Mega noi.

IV. ACCORDING TO YOOGIMUNI:

"இயம்பவே எளியோரை யிகழ்ச்சி சொல்லல்

ஏற்றமாம் பெரியோரை ஏவல் கொள்ளல்

புயம்பவே பொன்றனையே சோரஞ் செய்தல்

பொருள்தனையே பகிர்த்தல் பெருமை சொல்லல்

நயம்பவே நம்பினார்க்கு நட்டஞ் செய்தல்

நாட்டமா எந்நேரமும் பெண் போகித்தல்

பயம்பவே பயந்து வந்த பேரைக் காட்டல்

பழித்த போர் பிரமியத்திற் பாடாமே

பாடாக பெண் போக மிகவிரும்பிப்

பயின்றிட்டுப் பட்டினியே மிகவிருத்தல்

தாடாகத் தன் பாதத்தில் சூடு தாங்கல்

சரசமாய்க் காரத்தை மிகப் பொசித்தல்

ஊடாக உப்புரைப்புத் துவர்ப்பு மிஞ்சல்

உக்கிரமாம் பலபலவாம் விசேடம் செய்தல்

காடான மனக்கிலேசம் காரமான

கைத்தலோடு மிருக்கலிதுகாணுங் காணே"

-Yoogimuni vaidya chinthamani 800

1. Riduculating the downtrodden.
2. Commanding elders
3. Filching gold
4. Filfering others things
5. Self boasting
6. Bringing loss to others
7. Being thoughts of sexual intercourse always
8. Starvation for longtime
9. Walking without foot wear
10. Increased intake of spicy food, salty food, and astringents, pungents and bitter tasty foods.

V. According to T.V. Sambasivam pillai the chief causes of disease is

- Venereal disorder,
- Intemperate habits,
- Improper dietary Habits,
- Conceptional Defects,
- Any accidental Happening,
- Prostitution.

VI. According to Magalir Maruthuvam (pg No.124)

1. Due to Physiological factors,
2. Altered Sexual Indulgence causes Vellai noi.

TYPES AND CHARACTERS OF VELLAI NOI

ACCORDING TO AGASTHIYAR VAITHYA KAAVIYAM 1500:

வாத மேகம் மற்றும் சேத்தும மேகம்:

"விரும்பிய சிலைதாதுவும் வெளுத்திடில் வாதமேகம்

மரும்பிய உஷ்ணந்தானும் மயிலதன் நிறமேயானால்

திரும்பிய வையத்தாலே சேர்ந்திடும் மேகமாகும்

சுரும்பிய மூன்றாலப்பா தோன்றிடும் குணங்கள் கேளே.''

\- Poem 51

பித்த மேகம்:

''ஆச்சப்பா மேகம் கேளு அப்பனே பயித்திய ரோகம்

நீச்சப்பா மேகந்தன்னை நிசஞ் சொன்னேன் காணு

காச்சப்பா மஞ்சள் போலக் கவீணழந்தன்னை கண்டால்

வீச்சப்பா பித்தமேகம் விளம்பினார் விரும்பிக் காணே''

- Poem 50

According to the color of vaginal discharge Mega noi divided in to three types. In Vaatha megam the discharge is white in color. In Pitha megam the discharge is yellow in color. In Sethuma megam the discharge is greenish blue in color.

பித்த வாய்வு மேகத்தில் சேர்ந்தால்:

"கேளப்பா பித்தவாய்வு கெடியுடன் சேருமாகில்

தாளப்பா ஞானமான தமரிலே யெரித்துவேகும்

வீளப்பா நீரைக்கட்டும் விழும்பொசிந் துளியுமாறும்

பாளப்பா சிலநேரங்கள் பளிச்சென இறங்குந்தானே."-

Poem 52

In Mega noi, if there is pitha added then the symptoms are Burning sensation of vagina, absence of urination, drippling of urine, and sometimes pricking pain associated with micturition.

வாய்வு ஒதுங்கினால்:

"தானென்ற வாய்வு ஒதுங்கினால் தண்டிலே நோவுதானாம்

வானென்ற மந்தத்தாலே வாயுவில் புகுந்தேசாடும்

கானென்ற எரிச்சல் காணும் கல்லடைப்பாகும் பின்னை

மானென்ற வாதுவாய்வு மருவிடில் வெள்ளை காணே." –

Poem 53

வெள்ளை மிகுதியானால் இலட்சணம்:

''வெள்ளைதான் மெத்தவீழில் மேனியும் பொருமிக்காணும்

கள்ளமே சரீரமெல்லாம் கறுப்புடன் நரம்பு மோடும்

தள்ளவே தாதுநட்டந் தேகமு மிகுதியுண்டாம்

உள்ளது சொன்னோ நாமு முற்றுணர்ந்து அறிந்து கொள்ளே."

–Poem 54

If the Vaginal discharge is increased, then the symptoms are Body pain, blackening of skin, prominent veins on the skin, infertility present.

MUKKUTRAIYAL (PATHOLOGY):

Certain extrinsic and intrinsic factors are said to be causative factors, which alter the equilibrium of tridosha and produce the disease. Among the mukkutram, Pitham is the chief factor.

According to Theraiyar

"பகர்பித்த விந்தையலாது மேகம் வராது"

Ref. Noinadal Noimuthal nadal Part 1.

It denotes that alteration of pitham causes Mega diseases. Altered pitham affects Abanan, viyanan and devadhathan

Affected abanan alters the theyu pootham so it produces burning micturition, purulent discharge in the vagina, low back pain lower abdominal pain and constipation.

Affected viyanan and devadhathan alters the akaya pootham and leads to loss of appetite, fatigue, emaciation, itching on vulval region, sleep disturbances, and mental stress.

Diagnosis mainly related to three components namely

1) Poriyalarithal
2) Puzhanalarithal
3) Vinathal

Poriyalariyhal:

“Pori” means Organ of Perception namely

1) Skin
2) Tongue
3) Eyes

4) Ears
5) Nose

Pulanalarithal:

“Pulan” means Object of Sense namely

1) Touch
2) Taste
3) Vision
4) Hearing
5) Smell respectively.

“Pori” and “Pulan” with that of Physician’s “Pori” and “pulan”.

Vinathal: It is a method of enquiring about the details of the patient’s complaints from his own words or from their attenders.

These three components can be compared with that of interrogation and inspection. Besides this “Thottuparthal” (palpation) and Thattiparthal (percussion) are also used to examine the patients.

Another important diagnostic method is **“Envagai thervugal”**

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரமிவை மருத்துவராயுதம்"

According to Agasthiyar

"தொகுக்கலுற்று அட்டவிதப் பரிட்சை தன்னை
துலக்கமுறும் பண்டிதனே தெளிவாகப்
பகுத்தறிய நாடியை நீ பிடித்துப் பாரு
பகிர்கின்ற வார்த்தைப் பார் நாவை பாரு
வகுக்கரிய தேகமெனத் தொட்டுப் பாரு
வளமான சரீரத்தின் நிறத்தைப் பாரு
சகிக்கரிய மலத்தைப் பார் சலத்தை பாரு
சார்ந்த விழிதனைப் பார்த்து தெளிவாய் காணே"

–Agasthiyar vaithiya vallathi-600

According to Agasthiyar Gunavagadam:

"தரணியுள்ள வியாதிதன்னை யட்டாங்கத்தால்
தானறிய வேண்டுவது யாதோ வென்னில்
திரணியதோர் நாடி கண்கள் சத்தத்தோடு
தேகத்தினது ஸ்பரிசம் வருணம் நாக்கு
யிரண மல மூத்திர மிவைக ளெட்டும்
ணருளால் பெரியோர்கள் பாதம் போற்றிப்
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே"

According to Theraiyar:

"மெய்க்குறி நிறம் தொனி விழிநா
இரு மலம் கைக்குறி"

1) Naadi
2) Sparism
3) Naa
4) Niram
5) Mozhi
6) Vizhi
7) Malam
8) Moothiram

1. Naadi:

Naadi is the main diagnosis scale of the siddha system. It can be felt at one inch below the wrist on the radial laterally by means of palpation with the tip of index, middle and ring finger corresponding to vatham, pitham and kabam. Normally these three vital forces exist in the ratio 1:1/2:1/4. Derangement of this ratio leads to various disease entities.

In Vellai Noi the following Naadi nadai are seen commonly Vatham, Pitham, Vathapitham, Pitha vatham and sometimes Kaba pitham may be present.

According to sathaga naadi padalgal:

Pitha naadi:

"உறுதியுள்ள பித்தமது தோன்றில் வெப்பு
உட்ணவாயு வத்திசுர மதிசாரங்கள்
மறதியுடன் கிறுகிறுப்பு பயித்திய ரோகம்
வளர்சோகை யழலெரிவு காந்தல் கைப்பு
இருதயத்தில் கலக்கமது மறப்பு தாகம்
எழுங்கனவு மேயனைவு மயக்க மூர்ச்சை
சிறிதுபெரும்பாடு ரத்தம் **பிரமே கங்கள்**
சேர்ந்து மிகுபிணி பலவுஞ் சிறக்குந் தானே"

Vaatha naadi:

"வாதமெனும் நாடியது தோன்றில்
சீதமந்தமொடு வயிறு பொருமல் திரட்சி வாய்வு
சீதமுறுங் கிராணி மகோதரம் நீராமை
திரள்வாய்வு சூலை வலிகடுப்புத் தீரை
நீதமுறுங் கிருமி குன்மம் அண்டவாதம்
நிலையும் நீர்க்கிரிச்சரங்கள் **தந்துமேகம்**

பேதகமாம் உதரப் பிணி மூலரோகம்
பேசவெகுபிணிகளுமே பொருளதாமே"

Vaatha pitha naadi:

"பொருளான வாதத்தில் பித்தம் சேர்ந்து
பொருந்து குணங்களா முட்ணவாயு சக்தி
செரியாமை புளித்தேப்பம் பொருமல் நீரில்
சிவப்புமலம் பிடித்தலுருந் தாது நட்டம்
கருவான தேகமதில் உளைச்சல் சோம்பல்
கைகால் தறிப்பு நாகசக்கு மன்னம்
பரிவான ஊண்குறைதல் ருசிகேடாதல்
பலநோயும் வருத்தி வைக்கும் பாங்குதானே"

2. Sparisam:

Sparisam means touch. By touching the skin body temperature will be noted.

In Vellai noi body temperature is slightly increased and maintained as low grade fever.

3. Naa:

To rule out the color, coating and ulceration of the tongue.

In Vellai noi the tongue may be dry and coated. If anaemia present then the color of the tongue is pallor.

4. Niram:

To rule out the color of the tongue, eyes face and skin etc.

5. Mozhi:

To rule out the high or low pitched voice, Slurred speech or Incoherent speech, nasal speech, hoarseness of voice.

In vellai noi speech is normal and voice is medium pitched.

6. Vizhi:

Both motor & sensory functions of eye will be noted. Burning sensation of eyes Lacrimation, irritation, colour are also noted under this heading.

In vellai noi sometimes burning sensation of eyes will be noted.

7. Malam:

Quantity, colour, odour, constipation, diarrhea, presence of blood and undigested matter in the stools can be find out. In vellai noi Constipation may be noted.

8. Moothiram:

"வந்தநீர்க் கரிஎடை மணம் நுரை எஞ்சலென்
றைந்தியலுளவவை யறைகுது முறையே"

-Theraiyar Neerkuri Neikuri Nool

Moothiram consists of Neerkuri (Niram, Manam, Edai, Nurai, and Enjal) and Neikuri.

Neerkuri:

Niram	-	It indicates colour of urine
Manam	-	It indicates the smell of urine
Edai	-	It indicates specific gravity of urine
Nurai	-	It indicates frothy of urine
Enjal	-	It indicates quantity of urine

In addition frequency of micturition, burning micturitions, any abnormalities and associated vaginal discharge can be found out.

In vellai noi Burning micturition and painful micturition, and associated with purulent discharge can be noted.

Neikuri:

"அருந்துமாறிரதமும் அவிரோதமதாய்
அஃகல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக்கலசத் தாவியே காது பெய்து
ஒருமுகூர்த்தக் கலைக்குட்பட்டு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

Ref: Theraiyar Neerkuri Neikuri Nool.

Method:

Prior to the day of urine examination the patient is advised to take a balanced diet and the quantity of food must be proportionate to his appetite and should have a good sleep.

After waking up in the morning the first urine voided by the patient is collected in a glass container and is subjected to analysis with in 1 ½ hours.

A drop of gingley oil is dropped in to container without shake. The nature of the neikkuri should be noticed in direct sunlight.

Observation

I. Vatha neer :

"அரவென நீண்டின் அஃதே வாதம்"

When the drop of oil spreads like a snake it indicates Vatha neer.

II. Pitha neer:

"ஆழிபோற் பரவின் அஃதே பித்தம்"

When the drop of olil spreads like a ring it indicates pitha neer.

III. Kaba neer:

"முத்தொத்து நிற்கின் மொழிவதென் கபமே"

When the drop of oil remains as that of pearl it indicates kabaneer.

IV. Thontha neer:

"அரவிலாழியும் ஆழியில் அரவும் அரவில் முத்தும் ஆழியில் முத்தும் தோற்றில் தொந்த தோடங் களாமே"

When the drop of oil shows two shapes enclosed within one another it indicates thontha neer.

In vellai noi the neikuri spreads like a ring.

Thinai (Land & Place):

The geographical distribution of the land is classified into five regions.

1. Kurinji - Mountain and its surroundings.
2. Mullai - Forest and its surroundings.
3. Marutham - Fields and its surroundings.
4. Neithal - Sea and its surroundings.
5. Palai - Desrt and its surroundings.

Each region has its own character, which influence the inhabitants, physical, mental, economic, occupational and cultural activities. In each region some ailments are endemic based on the clinical features. Preventions and curative measures for these ailments are stated in medical literature.

Kalam (Seasons):

With reference to the position of sun, the year is divided into six seasons as follows.

1. Karkalam - Aavani and Puratasi (Aug-15 to Oct-14)

2. Koothir kalam - Aypasi and Kaarthigai (Oct-15 to Dec-14)
3. Munpani kalam - Margazhi and Thai (Dec-15 to Feb-14)
4. Pinpani kalam - Maasi and Panguni (Feb-15 to April-14)
5. Elavenil kalam - Chithrai and Vaikasi (April-15 to June-14)
6. Muthuvenil kalam - Aani and Aadi (June-15 to Aug-14)

According to climatic conditions in every season changes will occur in the land water, plants, animals, and human beings which will modify the physiology and make them susceptible to certain specific diseases into account of these changes, siddhars have advised to follow certain measures in the form of diet, purgation, exercise etc. to avoid the onset of this disease.

Udal vanmai:

Smartness, strength, vitality constitutes udal vanmai. It is classified into 3 types.

1. Iyarkai vanmai - Inherited immunity by birth.
2. Kala vanmai - Vitality that is generally found in different age
3. Cheyarkai vanmai - Improvement of vitality obtained by good habits, physical exercise and proper diet.

Mukkutrangal:

The anatomical and physiological units of the body that is vatham, pitham, and kabam are known as three vital forces. When they are affected then it is called as Mukkutrangal. Vatham is described as ten forms. Pitham and Kabam have been classified into five forms.

Vatham:

The word vatham not only implies wind but also comprehensive all the phenomenawhich comes under the functions of the central and sympathetic nervous system. Ten types of vatham are

1. Pranan
2. Abanan
3. Uthanan
4. Viyanan
5. Samanan
6. Nagan
7. Koorman
8. Kirugaran
9. Devathathan
10. Dhanajayan

In Vellai noi AbananViyanan and samanan are affected.

Affected Abanan produces burning sensation in the urethra, burning micturition, purulent discharge, pain in the lower abdomen, low back pain and constipation.

Affected Viyanan produces pain all over the body, loss of appetite, loss of weight, fatigue, itching, and altered sleep rhythm.

Affected Samanan produce loss of appetite.

Pitham:

Pitham does not essentially mean bile but signifies the function of the thermo genesis of heat production and metabolism, comprehensing in its scope. The process of digestion, colouration of blood and formation of various secretion and excretions which are either the means or the ends of tissue combustion.

Five types of Pitham:

1. Analagam
2. Ranjagam
3. Prasagam
4. Alosagam
5. Santhigam

In Vellai noi Anarpitham, Rantagam were affected. Affected anarpitham produces loss of appetite. Affected Ranjagam produces pallor of eyes, skin and nail buds.

Kabam:

Five types of Kabam are

1. Avalambagam,
2. Kilethagam,
3. Pothagam,
4. Tharpagam,
5. Santhigam

In Vellai noi Kilaethagam, tharpagam, and santhigam are affected. Avalambagam also affected due instability of other kabam.

Affected Kilethagam causes loss of appetite.

Affected tharpagam causes burning eyes.

Affected Santhigam causes low back pain.

Seven udal thathukal:

They are the basic principles, which constitute entire body.

1. Saram
2. Senner
3. Oon
4. Kozhuppu
5. Enbu
6. Moolai
7. Suronitham.

In Vellai noi Saram, seneer, oon, kozhuppu, Moolai, suronitham are affected.

Saram -Loss of appetite, fatigue, dryness of skin.

Senner -Weakness of the bidy, Anaemia.

Oon -Back pain

Kozhuppu -Emaciation

Moolai -Oliguria, Burning sensation.

Suronitham -Yellowish or white vaginal discharge.

Differential diagnosis:

Chronic cervicitis:

By the use of contraceptive devices for longtime, inflammation occurs.

Symptoms:

Vaginal discharge, low back pain, dysuria, polyuria.

Oopherities:

Vaginal discharge, Lower abdominal pain, constipation, Increased Body temperature, coated tongue, Menorrhagia.

MARUTHUVAM: (LINE OF TREATMENT)

"உற்றான் அளவும் பிணியளவுங் காலமுங்
கற்றான் கருதிச் செயல்" -குறள்

The treatment should be based on the age; body built of the patient, the severity of the diseaseand the period of the ailment. In Siddha system of medicine, treatment is not onlyfor cure of disease, but also the prevention and improving the body condition after treatment.
This is said as,

- Kappu (Prevention)
- Neekamn (Treatment)
- Niraivu (Restoration of wellbeing)

KAPPU (Prevention):

Siddha system has unequivocally stated that even during the time of conception. Some defects creep into fertilized embryo, which forms certain disease. Those diseases may be cured not only by medicine but by teaching the following habits.

1. Teaching good moral habits.
2. Avoid excessive sex indulgence.
3. Avoid pre and extra marital sex.
4. Avoid sex after taking oil bath and curd rice.
5. Avoiding stress and anxiety.
6. Always have good mental thoughts by doing meditation.
7. Avoiding the use of unhygienic undergarments.
8. Always wash the undergarments in a soap plus disinfectant solution.
9. Avoid urinary infection by taking more water.
10. Avoid increased intake of spicy, sour and salty foods.
11. Taking oil bath regularly.
12. Taking laxatives once in 6 months.

13. Always do yoga practice and prnayamam according to their physical and mental conditions.

Neekam:

According to Noi nadal and Noi muthal nadal a good physician should know the deranged kuttram and should treat the patient on the basis of altered kuttram.

"முப்பிணி மருவிமுறிவுகொள் குறிப்பை
தப்பாதறியும் தன்மையும் வாதபித்தவையப் பிரிவையு மவைதாம்
ஏறியிறங்கி இணைந்து கலந்து
மாறி மாறி வருந்து செய்கையாற் பிணி
நேர்மையறிந்து நீட்டு மருந்தே
சீரியதா மெனச் செப்புவர் சித்தரே"

-Ref: Noi naadal Noi muthal naadal part-1.

The aim of treatment is based on

To bring the Tridosham to normal

To treat the disease according to the symptoms by internal drugs.

For Regulating Tridosham:

"விரேசனத்தால் வாதம் தாழும்
வமனத்தால் பித்தம் தாழும்
நசிய அஞ்சனத்தால் கபம் தாழும்"

Vatha diseases can be brought down by “viraesanam”. For this laxatives and purgatives are given according to patient’s tolerance to drug and also the severity of the disease should be assessed.

Pitha diseases can be brought down by giving “vamanam” (Emetics) and kabha diseases can be brought down by “Anjanam” and “Nasiyam”.

In vellai noi Vatham and pitham is affected. So purgative medicine will be administered on the first day or before starting the specific treatment.

Medicine: Mega rajanga kirutham - 4ml twice a day before food for a period of 9 days twice a month.

Pathiyam:

During the course of treatment, the patient is advised to follow certain precautions regarding diet and physical activities. This form of medical advice in siddha system of medicine is termed as “PATHIYAM” which is very important in sidha system of medicine.

Pathiyam has been classified into itchapathiyam and kadum pathiyam

Itchapathiyam:

தேரையர் வெண்பா

"உலகிலிச்சா பத்தியங்கண் டீர்கூர மாங்கா
யலகினமைக் காய்கொத் தவரை-கலகமுனி
மந்தவகை கூழ்ப்பாண்ட மாகடுகெள் ளென்றோது
மீந்தவகை யீத்துண்ப தே"

சுந்தராந்தர் ஆயுள்வேத பொது லக்ஷணம்

"கடுகிநற்றிலத் தெண்ணெய்கூழ்ப் பாண்டங்கள் கடலை
வடிவதாகிய தெங்குமா வருக்கைநற் காயம்
மடிவிலாதவெள் ளுள்ளிகொள் புகையிலை மதுபெண்
இடதுபாகலோ டகத்திநீக் கிடலிச்சா பத்தியம்"

(Ref- Theraiyarvenba, suntharananthar ayul vetha pothu lakshanam in sigicharathna deepam pg 319,320).

Kadum pathiyam:

"கடுமை யென்றிடு பத்தியம் மூவர்வறுத் துண்டல்
ஆடைவிலா மறுபத்தித் துவர் வறுத்தருத்தல்
கொடுமை செய்புளி தனைச்சுட்டு கூட்டிட லன்றிப்
படியில் கத்தரி சிக்குரப் பிஞ்சினைப் பருகல்"

Pathiyam (diet) for Pitha disease:

Pathiyam for pitha disease as mentioned in pathartha guna chinthamni is as follows.

"கொம்மட்டி வாழைப்பன்னங் கொழுத்திய கரியினோடே
விம்மிய தண்ணீர்விட்டான் வேரெனுங் கிழங்கு சாந்தஞ்
செம்மைசேர் நெல்லிமுள்ளி சேருமில் மருந்தெல்லாமே
கம்மிய மித்ததிற்கு காலலென் றோது வாரே"

Niraivu (Restoration):

1. Reassurances of recovery were given to every patient.
2. Every patient was advised to follow strick diet restrictions, good moral behavior

Diet and Advice:

The following diet to be taken:

- ✓ Drink adequate water
- ✓ Leafy greens & vegetables
- ✓ Lady's finger
- ✓ Onion
- ✓ Ginger
- ✓ Steamed vegetables & vegetable salads
- ✓ Riped bananas
- ✓ Lemon or orange juice
- ✓ Pears Black plums
- ✓ Apple
- ✓ Gooseberry
- ✓ Dates
- ✓ Fig fruit
- ✓ Pomegranate
- ✓ Grapes
- ✓ Guava
- ✓ Whole wheat
- ✓ Brown rice
- ✓ Milk

- ✓ Butter milk
- ✓ Ghee
- ✓ Fenugreek
- ✓ Coriander seeds
- ✓ Cumin seeds

The following food should be avoided:

- Bitter gourd
- Chicken
- Meat
- Coconut
- Jack fruit
- Asafoetida
- Mango
- Brinjal
- Sesbanian leaves
- Mustard
- Sesame
- Tamarind
- Eggs
- Mushrooms
- Bread
- Sweets
- White sugar
- Tea
- Coffee
- Preserved cool drinks
- Oily & fried foods
- Sour foods

Avoid:

- Tobacco
- Alcohol
- Excessive lust

MODERN ASPECT

ANATOMY OF THE FEMALE GENITAL TRACT

The female genital tract may be divided into the external and internal genitalia. The external genital organs are vulva and the vagina. The internal genital organs are uterus, cervix, fallopian tubes, ovaries and other supporting structures.

The vulva:

The vulva comprises the following structures.

1. The Mons Pubis
2. The Labia Majora
3. The Labia Minora
4. The Clitoris
5. The Vestibule
6. The External Meatus
7. Bartholin's glands
8. The Hymen

The Mons pubis:

Mons pubis is a rounded eminence present in in front of the pubic symphysis. It is formed by accumulation of subcutaneous fat. It is covered with pubic hair. The hair bearing area has a nearly horizontal upper limit.

The Labia majora:

Labia majora are two thick folds of skin enclosing fat. They form the lateral boundaries of the pudendal cleft. Their outer surfaces are covered with hair, and inner surfaces are stutted with large sebaceous glands. The larger anterior ends are connected to each other below the mons pubis to form the anterior commisure. The area between the posterior commisure and the anus which is about 2.5 cm long constitutes the gynaecological perineum.

The Labia minora:

Labia minora are two thin folds of skin, which lie within the pudendal cleft. Anteriorly, each labium minus splits into two layers; the upper layer joins the corresponding layer of the opposite side to form the prepuce of the clitoris. Similarly the lower layers of the two sides join to form the frenulum of the clitoris. Posteriorly the two labia minora meet to form the frenulum of the labia minora. The inner surface of the labia minora contains numerous sebaceous glands.

The clitoris:

The clitoris is an erectile organ, homologous with the penis. However, it is not traversed by the urethra. It lies in the anterior part of the pudendal cleft. The body of the clitoris is made up of two corpora cavernosa enclosed in a fibrous sheath and partly separated by an incomplete pectiniform septum. The surface of the glans is highly sensitive and plays an important role in sexual responses.

The Vestibule:

The vestibule of the vagina is the space between the two labia minora. The external urinary meatus opens into it. The boat shaped Navicular fossa is situated in front of the fourchette and bounded in front by the hymen.

Bulbs of the vestibule:

These are two oval bodies of erectile tissue that correspond to the two halves of the bulb of the penis. The bulbs lie on either side of the vaginal and urethral orifices, superficial to the perineal membrane. The tapering anterior ends of the bulbs are united in front of the urethra by a venous plexus, called the bulbar commisure. The expanded posterior ends of the bulbs partly overlap the greater vestibular glands.

Greater vestibular glands of Bartholin:

Greater vestibular glands are homologous with the bulbourethral glands of Cowper in the male, but unlike them these lie in superficial perineal space at the vaginal orifice. They are overlapped by the posterior ends of the bulbs of the vestibule. Each gland has a long duct about 2 cm long which opens at the side of the hymen, between the hymen and the labium minus.

Hymen:

This is a membrane found in the lower part of vagina. An intact hymen is a sign of virginity. It has an opening for the menstrual flow. If the opening is absent in the hymen it is called imperforate hymen. Hymen is torn or ruptured during sexual act.

The Vagina:

Synonyms: kolpos = vagina

The vagina is a fibromuscular canal, forming the female copulatory organ. The term vagina means a sheath. The vagina extends from the vulva to the uterus, and is situated behind the bladder and the urethra, and in front of the rectum and anal canal.

Direction:

In the erect posture, the vagina is directed upwards and backwards with a slight forward convexity, making an angle of about 45 degrees with the uterus. However, these angulations vary with the condition of the bladder and rectum. In the supine position, it makes an angle of about 75 degrees with the horizontal plane.

Size and shape

The anterior wall of the vagina is about 8 cm and the posterior wall about 10 cm long. The diameter of the vagina gradually increases from below upwards. The upper end of vault is roughly 5 cm twice the size of the lower end (2.5cm). However, it is quite distensible and allows passage of the head of the foetus during delivery. The lumen is circular at the upper end because of the protrusion of the cervix into it. Below the cervix, the anterior and posterior walls are in contact with each other, so that the lumen is a transverse slit in the middle part, and is H – shaped in the lower part. In the virgin, the lower end of the vagina is partially closed by a thin annular fold of mucous membrane called the hymen. In married women the hymen is represented by rounded elevations around the vaginal orifice, the caruncular hymenale.

Fornices of vagina:

The interior of the upper end of the vagina or vaginal vault is in the form of a circular groove that surrounds the protruding cervix. The groove becomes progressively deeper from before backwards and is arbitrarily divided into four parts called the vaginal fornices. The anterior fornix lies in front of the cervixand is shollowest. The posterior fornix lies behind the cervix and is deepest. The lateral fornices lay one on each side of the cervix.

Arterial supply:

The vagina is a very vascular organ, and is supplied by the following arteries: 1) the main artery supplying it is the vaginal branch of the internal iliac artery. 2) In addition, the upper part is supplied by the uterine artery. The lower part by the middle rectal and internal pudendal arteries. Branches of these arteries anastomose to form anterior and posterior midline vessels called the vaginal azygos arteries.

Venous drainage:

The rich vaginal venous plexus drains into the internal iliac veins through the vaginal veins which accompany the vaginal arteries.

Lymphatic drainage:

Lymphatics from the upper one-third of the vagina drain into the external iliac nodes; from the middle one-third into the internal iliac nodes; and from the lower one-third into the medial group of superficial inguinal nodes.

Nerve supply:

1) The lower one-third of the vagina is pain sensitive and is supplied by the pudendal nerve through the inferior rectal and posterior labial branches of the perineal nerve.
2) The upper two-thirds of the vagina are pain insensitive and are supplied by sympathetic L1, L2 and parasympathetic segments S2, S3 nerves derived from the inferior hypogastric and uterovaginal plexuses. Sympathetic nerves are vasoconstrictor and parasympathetic nerves vasodilator. The fibers which accompany the vaginal arteriesc form the vaginal nerves.

Structure of vaginal wall:

The vaginal wall consists of

1) Mucosa – Nonkeratinized stratified squamous epithelium
2) Submucosal layer – Lamina propria- loose connective tissue.
3) A Mucosal layer – Outer longitudinal & an inner circular layer
4) Outer fibrous coat is the usual connective tissue.

The Vaginal secretion:

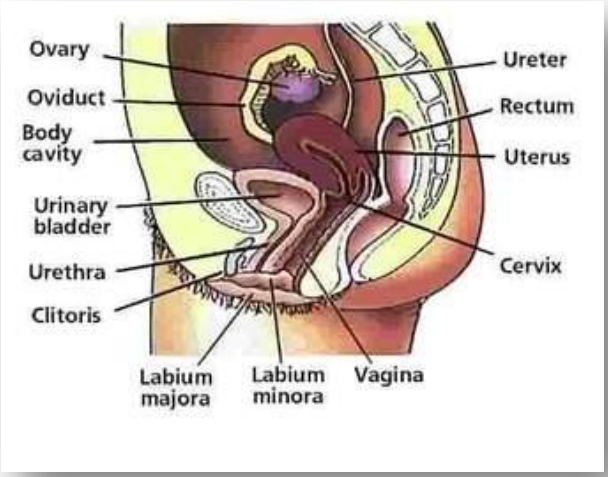
The vaginal secretion is small in amount in healthy women, and consists of white coagulated material. The top layers are rich in glycogen and some of these squamous cells are shed and acted on by the gram positive Dodrelein bacilli present in the vagina, converting this glycogen into lactic acid. This action is responsible for maintaining the PH of the vagina around 4.5 and preventing the growth of pathogenic organisms. Because of its protective function, the doderline bacillus is considered a vaginal police man. However with menopause and also prior to puberty and vaginal mucosa is thin and devoid of glycogen due to the absence of oestrogenic stimulus, and hence the PH of the vagina is alkaline.

Normal vaginal flora:

The microflora of normal vaginal secretions is characterized by a predominance of lacto bacilli, primarly acidophilic lacto bacilli. Usually an additional 5 to 15 bacterial species are also normally cultured from the vagina. G.vaginalis can be found in >50% of normal healthy women.

The vaginal flora can be divided in to aerobic and anaerobic organisms. Common aerobic facultative organisms found include lacto bacilli, staphylococcus epidermis, streptococcal and G. vaginalis. The anaerobic organism commonly found includes bacteroides species, B.bivius and peptostreptococcus. Mycoplasma hominis can be found in 20%- 50% and Ureaplasma urealyticum can be found in 50% to 70% of sexually active women. In women with normal vaginal flora, lactobacillus species account for >95% of the total organisms present.

The Uterus:



The uterus is pyriform in shape. And it measures about 7.5cm×5cm×2.5cm. It weighs about 30 to 40gms. It is divisible in to upper expanded part called the body and a lower cylindrical part called the cervix. The junction of these two parts is marked by a circular constricition. The body forms the upper two thirds of the organ, and the cervix forms the lower one third.

Normal position and angulation:

Normally, the long axis of the uterus forms an angle of about 90 degrees with the long axis of the vagina. The angle is open forwards. The forward bending of the uterus related to the vagina is called ante version. The uterus is also slightly flexed on itself: this is referred to as ante flexion. The angle of ante flexion is 125 degree. Roughly the long axis of the uterus corresponds to the axis of the pelvic inlet, and the axis of the vagina to the axis of the pelvic cavity and of the pelvic outlet.

Communications:

Superiorly, the uterus communicates of each side with the uterine tube, and inferiorly with the vagina.

Body of the uterus:

The body has a fundus, two surfaces, anterior or vesicle. And posterior or intestinal; and two lateral borders.

The fundus is formed by the free upper end of the uterus. The fundus lies above the openings of the uterine tubes. It is convex like a dome. It is covered with peritoneum and is

directed forward when the bladder is empty. The fertilized oocyte is usually implanted in the posterior wall of the fundus.

The anterior or vesicle surface is flat and related to the urinary bladder. It is covered with peritoneum and forms the posterior or superior wall of the uterovesical pouch.

The posterior intestinal surface is convex and is related to coils of the terminal ileum and to the sigmoid colon. It is covered with peritoneum and forms the anterior wall of the recto uterine pouch.

Each lateral border is rounded and convex. It provides attachment to the broad ligerment of the uterus which connects it to the lateral pelvic wall. The uterine tube opens into the uterus at the upper end of this border. This end of the border gives attachment to the round ligament of the uterus, anteroinferior to the tube; and to the ligament of the ovary posterinferior to the tube. The uterine artery ascends along the lateral border of the broad ligament.

In sagittal section, the cavity of the body of the uterus is seen as a mere slit because the uterus is compressed anteroposteriorly. In coronal section, the cavity is seen to be triangular in shape, the apex being directed downwards. At the apex, the cavity becomes continuous with the canal of the cervix. The junction is called internal os.

Cervix of the uterus:

The cervix is the lower cylindrical part of the uterus. It is about 2.5cm long. The lower part of cervix projects into the anterior wall of the vagina which divides it into supravaginal and vaginal parts.

The supravaginal part of the cervix is related a) Anteriorly to the bladder; b) Posteriorly to the rectouterine pouch, containing coils of intestine and to the rectum and c) on each side, the ureter and to the uterine artery, embedded in parametrium.

The vaginal part of the cervix projects into the anterior wall of the vagina. The cervical canal opens into the vagina by an opening called external os. In nulliparous women the external os is small and circular. However, in multiparous women, the external os is bounded by anterior and posterior lips, both of which are in contact with the posterior wall of the vagina.

The cervical canal is fusiform shape. The walls of cervical canal shows mucosal folds which resemble the branches of a tree called the arborvitae uteri. The folds in the anterior and posterior walls interlock with each other and close the canal.

Ligaments of the uterus:

Peritoneal ligaments

These are mere peritoneal folds which do not provide any support to the uterus.

1) The anterior ligament consists of the uterovesical fold of peritoneum.
2) The posterior ligament consists of the rectovaginal folds of peritoneum.
3) The right and left broad ligaments are folds of peritoneum which attach the uterus to the pelvic wall.

The broad ligament contains the following structures.

1) The uterine tube.
2) The round ligament of the uterus.
3) The ligament of the ovary.
4) Uterine vessels near its attachment to the uterus.
5) Ovarian vessels in the infundibulopelvic ligament.
6) The uterovaginal and ovarian nerve plexuses.
7) Epooophoron.
8) Paroophoron.
9) Some lymph nodes and lymph vessles.
10) Dense connective tissue or parametrium present on the sides of the uterus.

Fibro muscular ligament

The fibro muscular ligaments are: 1) Round ligaments of the uterus, 2) transverse cervical ligaments 3) Utero sacro ligaments.

Arterial supply:

The uterus is supplied by two uterine arteries and the ovarian arteries. The uterine artery is a branch of the anterior division of the internal iliac artery. Apart from the uterus the artery also gives branches to vagina, medial two thirds of the uterine tube the ovary the ureter and the structures present in the broad ligament.

Venous Drainage:

The veins form a plexus along the lateral border of the uterus. The plexus drains through the uterine, ovarian and vaginal veins into the internal iliac veins.

Lymphatic drainage:

Lymphatics of the uterus begin at three inter communicating networks, endometrial, myometrial and subperitoneal. These plexuses drain into lymphatics on the side of the uterus. Of

these, the upper lymphatics from the fundus and upper part of the body drain mainly into the aortic nodes, and only partly to the superficial inguinal nodes along the round ligament of the uterus. The lower lymphatics from the cervix drain into the external iliac, internal iliac and sacral nodes. The middle lymphatics from the lower part of the body drain into the external iliac nodes.

Nerve supply:

The uterus is richly supplied by both sympathetic and para sympathetic nerves, through the inferior hypogastric and ovarian plexuses. Sympathetic nerves from T12, L1 segment of spinal cord produce uterine contraction and vasoconstriction. The parasympathetic nerves (S2, S3, and S4) produce uterine inhibition and vasodilatation. Pain sensation from the body of the uterus passes along sympathetic nerves, and from the cervix, along the parasympathetic nerves.

The structure of the uterus:

The wall of the uterus consists of 3 layers.

1) Outer peritoneal coverings or Perimetrium.
2) The middle muscular layer or Myometrium.
3) The inner mucosa or Endometrium.

Perimetrium:

It is incomplete. Anteriorly the whole body of the uterus is covered with peritoneum. The peritoneum is reflected on the bladder at the level of the internal os.

Posteriorly the whole of the body is covered by peritoneum. Laterally peritoneum is incomplete because of the insertion of the fallopian tubes, the round and ovarian ligaments into the uterus.

Endometrium:

The endometrium is the special epithelial lining. The surface of the epithelium is made up of glands and stroma. The endometrium varies in thickness during menstrual cycle and forms decidua during pregnancy in response to the hormones. The endometrium of the body of the uterus can be divided into two zones; a superficial termed the functional layer, and a deeper one termed the basal layer, which lies adjacent to the myometrium.

The vascular system of the endometrium is of great importance. Two types of arteries supply the endometrium. One of these is restricted to the basal third and consists of small straight and short arteries. The superficial two thirds of the endometrium are supplied by coiled arteries.

Myometroium:

It is the thickest of the 3 layers of the wall of the uterus. It again consists three layers.

1) Outer longitudinal layer, which has a detrusor action during labour.
2) The middle thick vascular layer which by virtue of its being arranged in a figure of eight around the vessels has a haemostatic effect to prevent post-partum hemorrhage.
3) The inner circular layer, which is seen mostly around the tubal orifices, the internal and external os and probably, has a sphincteric action.

Supporting structures of the uterus:

1) Broad Ligament:
   It stretches the lateral border of uterus wall of pelvis, they encloses the uterus. Along the upper border of broad ligament and fallopian tubes are situated to the posterior wall of ligament the ovaries are attached. Lower border of ligament is related to the floor of the pelvis.
2) Round Ligament:
   One on each side of the uterus. They pass to the side of pelvis through the inguinal canal to end by fusing the majora.
3) Two uterosacral ligament:
   Originate from the posterior part of cervix and vagina pass backward one on each side of rectum to the sacrum.
4) Transverse cervical or cardinal or Mackendrort's ligament:
   Originate from side of the cervix and vagina pass to the side of pelvic wall.

5) Pubocervical Fascia:
   It extends forward from transverse cervical ligaments on each side of the bladder to the posterior surface of pubic bone.

Blood supply of Uterus:

Uterus is supplied by uterine arteries and branch of internal iliac artery. Venous plexus of uterus drain into internal iliac vein. Deep and superficial lymphoid of uterus open into aortic lymphnodes.

Fallopian tubes or Oviducts:

It lies in the free border of broad ligament. This part is called as mesosalpinx. It is 10 cm in length. Its lateral end opens into peritoneal cavity through its abdominal ostium.

Parts:

It consists of four portions.

1) **Infundibulum:**

Lateral end of the uterine tube is funnel shaped is called as infundibulum. It has a finger shaped process called fimbriae. One of the fimbriae is longer than other fimbriae are attached to the ovary. It is known as ovarian fimbriae.

2) **Ampulla:**

The part, medial to the infundibulum is called ampulla. It is the longest and largest part of the uterine tube. Fertilization normally occurring in ampulla. After that the zygote moves towards the fundus of uterus within 72 hours.

3) **Isthumus:**

The part, medial to the ampulla is called as isthumus. It is narrow rounded part. It forms medial one third of uterine tubes.

4) **Intramural part:**

It is 1 cm long, lies within the uterine wall. It opens into uterine cavity by uterine ostium.

Functions of the tube:

1) Conduction of ovum from ovary.
2) Conduction of sperm
3) Fertilization and formation of zygote occurs in the tube.
4) Migration of zygote.

If the tube is blocked by disease or ligation leads to sterility. Sometimes the block may be partial and the fertilized ovum may get arrested in the tube or sometimes fertilized ovum does not reach the uterus within72 hours. So the zygote develops in the tube, resulting in tubal pregnancy. It may leads to rupture of the tube.

Blood supply of the tube:

Supplied by uterine artery and lateral part of tube is supplied by branches of ovarian artery. Lymph nodes are drain in to pre aortic nodes.

The ovary:

Ovaries are female gonads. They correspond with testis of male. The ovaries are two in number. They lie on either sides of the uterus. The ovaries are attached to the broad ligaments of the uterus. Each is an ovoid structure about 3.5cm×2cm×1.5cm.

Structure and functions of the ovary:

The ovary is covered by germinal epithelium. It consists of cortex and medulla. The cortex has ovarian follicle. One follicle matures every month and this matured ovarian follicle is known as graffian follicle. The ovum is released by the rupture of the follicle. Liberation of an ovum from the ovary is called ovulation. It occurs on or about the 14^{th} day of a 28^{th} day

menstrual cycle. After the ovum is liberated the ovarian follicle is converted into a structurecalled the corpus luteum.

The hormone oestrogen is secreted by the cells present in wall of the ovarian follicles. Another hormone, progesterone is produced by the corpus luteum.

The medulla of the ovary is vascular and it has soft tissue and blood sinusoids.

LEUCORRHOEA

DEFINITION:

The term leucorrhoea should be restricted to those conditions when the normal vaginal secretion is increased in amount. In such patients there will be no excess of leucocytes present when the discharge is examined under the microscope, and the discharge is macroscopically and microscopically non-purulent.

Leucorrhoea is strictly defined as an excessive normal vaginal discharge. The symptom of excessive is a subjective one with individual variations, while to declare it to be normal and not an infective one, requires clinical and laboratory investigations.

The term Leucorrhoea should fulfil the following criteria:

The excess secretion is evident from persistent vulval moistness or staining of the undergarment (brownish yellow or drying) or need to wear a vulvalpad.
It is a non-purulent and non-offensive. It is non-irritant and never causes purities.

PATHO PHYSIOLOGY:

Normal vaginal secretion:

The origin and nature of the normal vaginal secretion during the reproductive period has been described below.

The physiologic basis involved in normal vaginal secretion is dependent on the endogenous estrogen level. With the rising estrogen level, there is abundant secretory activity of the endo cervical glands and the superficial vaginal epithelium becomes rich in glycogen.

The mucoid secretion from the cervical glands is normally small in amount. The carbohydrate radicle of the glycoprotein mucin is split off and fermented into lactic acid.

If however, the mucus is secreted in excess, it pours out at the vulva.

The excessive secretion is due to:

- Physiological excess
- Cervical cause (Cervical leucorrhoea)
- Vaginal cause (Vaginal leucorrhoea)

Physiologic excess:

During puperty: Due to increased level of endogenous oestrogen.

During Menstrual cycle: Around ovulation- peak rise of oestrogen-increase in secretory activity of the cervical glands. Premenstrual pelvic congestion and increased mucus secretion from the hypertrophied endometrial glands.

Pregnancy: There is hyperoestrinism with increased vascularity. This leads to increased vaginal transudate and cervical gland secretion.

During sexual excitement: When there is abundant secretion from the Bartholin glands.

CERVICAL CAUSE:

Mucous discharge from the endocervical glands increases in such conditions as chronic cervicitis, cervical erosion, mucous polyp, and ectropion (cervical glands are exposed to the vagina). When the mucous secretion of the cervix is produced in excess, it undergoes little change in the vagina, and appears as mucoid discharge at the vulva.

VAGINAL CAUSE:

This form of leucorrhoea is seen when the discharge originates in the vagina itself as a transduction through the vaginal walls. Almost all the lactic acid of the healthy vagina is formed from the glycogen contained in the keratinized cells of the vaginal mucosa and the vaginal portion of the cervix.

These cells are constantly being desquamated, when their glycogen liberated is fermented by Doderlein's bacilli, which produces lactic acid. This process is under the control of oestrogen, the level of which determines the PH of the vagina.

Local congestive states of the pelvic organs such as pregnancy, acquired retroversion and prolapsed congested ovaries, chronic pelvic inflammatory disease and even chronic constipation associated with a sedentary occupation are all reasonable causes of an increased vaginal secretion.

DIAGNOSIS:

Vulval inspection reveals:

White or creamy discharge and No evidence of pruritus

Bimanual including a speculam examination reveals:

Either a negative pathology

Associated pelvic lesions mentioned earlier causing cervical or vaginal leucorrhoea.

To exclude the infective nature, the discharge is subjected to microscopic examination for detection of pus cells. If the pus cell is not detected, it is considered as a case of true leucorrhoea. If however pus cells are detected, further investigations are to be carried out to identify the organism from the discharge provided neoplasm and foreign body are excluded

These examinations include:

- Hanging drop preparation
- Clue cells
- Gramstain
- Culture

SPECIFIC VAGINAL INFECTIONS

If the strict definition of leucorrhoea is accepted as an excessive vaginal secretion in which the primary cause is not infective, any vaginal discharge which is frankly purulent and contains pus cells and form which the causative organisms can be isolated and cultured should be considered as due to specific vaginal infection.

Specific vaginal infection comprises

1) Gonococcal
2) Trichomonal
3) Monilial
4) Chlamydial and
5) Bacterial vaginosis

It is observed that 50% vaginitis is due to bacterial vaginosis, 20-25% vaginitis due to monilial infection and 15-20% due to trichomonal infection. Since most of these are sexually transmitted.

TRICHOMONIASIS

Vaginal trichomoniasis is the most common and important cause of vaginitis in the child bearing period. In clinical practice, this is amongst the most common. Nearly half the patients who complain of pruritus vulvae harbour this organism. It is almost entirely a disease of childbearing era, though young girls and postmenopausal women are not at all immune.

There is no doubt that this infection is sexually transmissible but, in some instances, it can be acquired by an inadequate hygiene or the use of an infected person's towels, bath or clothes. Its ingress to the vagina is favoured by a low general resistance and when the PH is raised as during a menstrual period (pH 5-6). It is not uncommon during pregnancy and is often associated with gonococcal infection.

Epidemiology:

Trichomoniasis is a cosmopolitan disease usually transmitted by sexual intercourse.

It is estimated that 3 million women in the United States and 180 million worldwide. Acquire this disease annually and 25% of sexually partners are also parasitized at least transiently.

Infection is rare in adult virgin, where as rates as high as 70% are seen among prostitutes, sexual partners of infected patients and individuals with other venereal diseases.

In women, the peak incidence of trichomoniasis is between 16 and 35 years of age, but there is still a relatively high prevalence in the 30 to 50 year age group.

Non venereal transmission is uncommon. Transfer of organisms on shared wash clothes, may explain, in part the high frequency of infection seen among institutionalized women.

AETIOLOGY

TRICHOMONAS VAGINALIS

The causative organism is Trichomonas *vaginalis*. It is a pear shaped unicellular flagellate protozoa. It is actively motile, slightly larger than a leucocyte and is anaerobic.

Three types of trichomonas are known, namely, Tr.*buccalis,* which is a normal inhabitant of the mouth; Tr.*hominis,* a normal inhabitant of the anal canal and rectum; and Tr.*vaginalis*, which is found in the vagina. It has been shown by transplantation experiments that Tr.*buccalis* and Tr.*hominis* are unable to survive in the human vagina.

Tr.*vaginalis* measures 20 micron long and 10 micron wide. It has got four anterior flagellae and a spear like protrusion at the other end with an undulating membrane surrounding its anterior two-third. It is actively motile.

MODE OF TRANSMISSION:

The organism is predominantly transmitted by sexual contact. The male harbours the infection in the urethra and prostate. The transmission may also be possible by toilet articles from one woman to the other or through examining gloves. The incubation period is 3 to 28 days.

In women the organism is found in the vagina, urethra, and para-urethral glands. While the urinary tract is the sole site of infection in less than 5% of cases, urethral infection is present in 90% of episodes. In adults, transmission is almost exclusively sexual. Due to site specificity, infection can only follow intra vaginal or intra urethral inoculation of the organism.

CLINICAL FEATURES:

- Twenty percent remain asymptomatic; others develop symptoms 4-28 days following sexual contact with an infected partner, or infected material, like towel or toilet.
- There is sudden profuse and offensive vaginal discharge often dating from the last menstruation. There is presence of urinary symptoms such as dysuria and frequency of micturition
- 10 to 50% of infected women are asymptomatic. In those with symptoms, these include vaginal discharge, vulval itching, dyspareunia, or offensive odour. Occasionally, the presenting complaint is lower abdominal discomfort.
- Vaginal discharge occurs in up to 70% of case, varying in consistency from thin and scanty to profuse and thick.
- The classical frothy yellow discharge occurs in 10 to 30% of women. Approximately 2% of patients will have strawberry cervix appearance to the naked eye.
- Higher rates are seen on colposcopic examination. No abnormalities will be seen in 5 to 15% of women on examination.
- There is increasing evidence of that Trichomonas vaginalis infection can have a detrimental outcome on pregnancy, and is associated with preterm delivery and low birth weight.

PATHOLOGY:

In about 25% of women in the reproductive period, the parasite harbour in the vagina in asymptomatic state. When the local defense is impaired during and after menstruation, after sexual stimulation and following illness the pH of the vagina is raised to 5.5 -6.5. At this level of pH the trichomonads thrive. The organisms usually lie in between the rugae and produce surface inflammatory reaction when the defense is lost. In about 75% of cases the organism can be isolated from the urethra, skene's tubules or even from the Bartholin's glands.

ON EXAMINATION:

- There is thin, greenish yellow and frothy offensive discharge per vagina.
- The vulva is inflamed with evidences of pruritus.
- Vaginal examinations may be painful. The vaginal walls become red and inflamed with multiple punctuate haemorrhagic spots.
- Similar spots are also found over the mucosa of the portio vaginalis part of the cervix on speculum examination giving the appearance of straw berry.

Complications:

Some of the complications of *T. vaginalis* in women include: preterm delivery, low birth weight, and increased mortality as well as predisposing to HIV infection, and cervical cancer *T. vaginalis* has also been reported in the urinary tract, fallopian tubes, and pelvis and can cause pneumonia, bronchitis, and oral lesions.

Trichomonas vaginalis infection in males has been found to cause asymptomatic urethritis and prostatitis. It has been proposed that it may increase the risk of prostate cancer.

DIAGNOSIS:

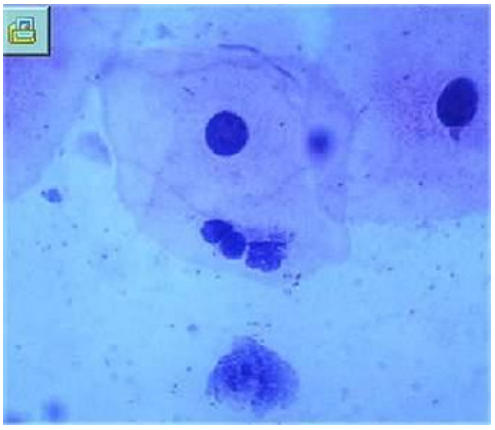
- Direct observation by wet mount or acridine orange staining is approximately 70% sensitive compared with culture in females. Microscopy T.vaginalis should be performed as soon as possible after the sample is taken, as motility diminishes with time.
- Identification of the trichomonads is done by hanging drop preparation. If found negative even on repeat examination, the conformation may be done by culture.
- Culture of the discharge collected by swabs in Kupferberg's or Feinberg Whittington medium.
- Culture techniques are still regarded as the most sensitive and specific. Culture media is varying in efficiency, but diamond TYM medium (Medium Tripticase, Yeast extract maltose) or modified version is among the best.

- PCR based diagnostic test s have been developed recently, and sensitivities and specificities approaching 100% have been reported. No PCR assay for T.vaginalis is currently on the market.
- Trichomonads are sometimes reported on cervical cytology, however, a Meta analysis has shown that while it has good specificity, the weighted mean sensitivity was only 58%. In such cases it is prudent to confirm the diagnosis, preferably by culture of vaginal secretions.

IDENTIFICATION OF ORGANISM IN SLIDE:

The material is dropped over a slide and then mixed with one drop of normal saline. It is then covered with a coverslip. Actively motile trichomonas can be seen under microscopic easily. It can be effectively visualized after staining with 1% of brilliant cresyl violet, lucicytes and other bacteria will not take up the dye.

TRICHOMONAS VAGINALIS



CANDIDAL VAGINITIS

It is caused by yeast like micro organism called *Candida* or *Monilia*. The most common species causing human disease is *Candida albicans*, which is gram positive and grows in acid medium. It may be sexually transmitted. Almost 25% women harbour *Candida* in the vagina, these are often asymptomatic.

CANDIDA ALBICANS

Risk factors:

These include promiscuity, immunosuppression, and pregnancy, steroid therapy, following long-term broad spectrum antibiotic therapy, oral contraception pills, diabetes mellitus, poor personal hygiene and obesity.

Clinical features:

Pruritus vulva is the cardinal symptom. It is often accompanied by vaginal irritation, dysuria, or both, and passage of thick curdy or flaky discharge.

Speculum examination reveals vaginal wall congestion with curdy discharge often visible at the vulval mucocutaneous junction and in the posterior fornix.

Diagnosis:

It is essentially based on clinical findings. But the diagnosis can be confirmed on microscopic examination of a smear of the vaginal discharge treated with 10% KOH solution which dissolves all other cellular debris, leaving the mycelia and spores of the *candida* in bold relief.

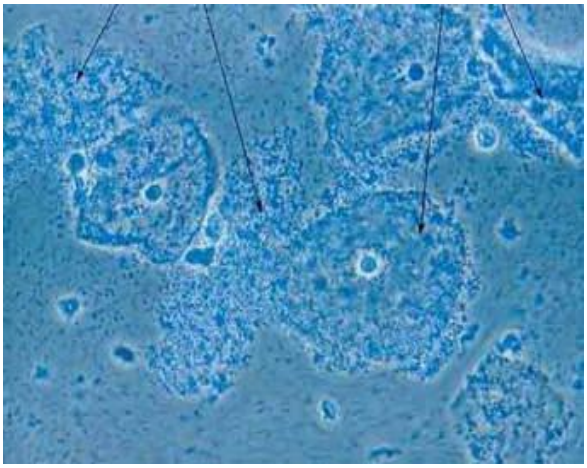
Gram staining of the discharge or Pap smears may also reveal presence of *candida.*

Culture on Sabouraud's agar or Nickerson's medium helps to identify *Candida.*

BACTERIAL VAGINOSIS

Bacterial vaginosis is termed vaginosis rather than vaginitis, because it is associated with alteration in the normal vaginal flora rather than due to any specific infection.

BACTERIA ON CULTURE



There is a considerable decrease in the number of lactobacilli in the vaginal discharge with 100 fold increase in growth of other anaerobic bacteria. Since lactobacilli release hydrogen peroxide toxic to other bacteria, reduction in their number allow other bacteria, i.e. aerobic and anaerobic bacteria to grow.

These are *Haemophilus vaginalis*, *Gardnerella*, *Mobiluncus* and *Mycoplasma hominis*. The *Mobiluncus* is a gram-positive curved rod with a characteristic corkscrew spinning anaerobe. The bacterial vaginosis is therefore a Polymicrobial condition.

It is not sexually transmitted with a variable incubation period. About 50% women are asymptomatic carriers of infection, but majority complain of vaginal discharge without itching.

The characteristic of vaginal discharge are:

- ✓ White, milky, non-viscous discharge adherent to the vaginal wall.
- ✓ PH of the discharge is more than 4.5.
- ✓ Fishy odour when mixed with 10% KOH is due to amino-metabolites from various organisms (amine or whiff rest).
- ✓ Presence of clue cells-the epithelial cells have fuzzy border due to adherence of bacteria.
- ✓ Increased number of *Gardnerella vaginalis* and other organisms and reduced number of lactobacilli, and leucocytes.
- ✓ The woman has minimal vulval irritation.

Diagnosis:

The diagnosis is based on wet smear and culture.

The smear reveals clean background with few inflammatory cells and other organisms, but scanty lactobacilli.

Many epithelial cells present a granular cytoplasm caused by small gram-negative bacilli adhering on their surface, so called clue cells.

Free floating clumps of Gardnerella are seen.

Complication:

This infection can cause PID, Chorioamnionitis, premature rupture of membrane (PROM), and preterm labor.

MATERIALS AND METHODS

MATERIALS AND METHODS

TITLE:

Clinical evaluation of Siddha drug **"Mega Rajanga kirutham" (internal) in the treatment of VELLAI NOI (Leucorrhoea).**

BACK GROUND

The development of nation lies in the empowerment of women. A Healthy mother brings forth a healthy baby. Women in India make approximately 50% of the population. Their socioeconomic and health statuses are considerably very low. Vellai noi (Leucorrhoea) is one of the sexually transmitted disease which affects women commonly and frequently.

Trichomoniasis is a cosmopolitan disease usually transmitted by sexual intercourse.

It is estimated that 3 million women in the United States and 180 million worldwide. Acquire this disease annually and 25% of sexually partners are also parasitized at least transiently.

Infection is rare in adult virgin, where as rates as high as 70% are seen among prostitutes, sexual partners of infected patients and individuals with other venereal diseases.

In women, the peak incidence of trichomoniasis is between 16 and 35 years of age, but there is still a relatively high prevalence in the 30 to 50 year age group.

The signs and symptoms of Vellai noi can be correlated with Leucorrhoea in modern science. The incidence of velai noi was found in women irrespective of their socio- economic status. More number of cases is recorded in OPD of Ayothidoss pandithar hospital, NIS. So I have decided to choose Leucorrhoea (Vellai noi) as my dissertation topic.

I have chosen Mega rajanga kirutham (Ref.Sigicha rathna deepam) to treat the vellai noi. As per literature evidence the ingredients of the trial drug possess anti microbial & anti inflammatory activity which cures vellai noi.

Aims

a. Primary Aim:

To estimate the efficacy of Mega rajanga kirutham in the treatment of vellai noi (Leucorrhoea)

b. Secondary Aim:

- To study the siddha co factors related to the disease.
- To study the pharmacological activity of the trial drug
- To study the physico chemical analysis of the trial drug

STUDY DESIGN AND CONDUCT OF STUDY:

Study type: An open Clinical trial

Study place: OPD and IPD of Dept of Maruthuvam and Dept of Magalir maruthuvam, National institute of siddha, Tambaram –sanatorium, Chennai-47.

Study period: 12 months.

Duration of drug administration: 9 days twice a month (18 days).

Study population: The patient who are attending the OPD & IPD of Department of Maruthuvam and Department of Magalir Maruthuvam, Ayothidoss pandithar hospital, National institute of siddha, Tambaram- sanatorium, Chennai-47.

Sample size: 40 patients

Study drug: Mega rajanga kirutham

Dosage: 4 ml, twice a day before food.

STUDY SUBJECT SELECTION:

When patients reporting at OPD of dept of Maruthuvam & Magalir maruthuvam, Ayothidoss pandithar hospital who satisfies the inclusion and exclusion criteria will be subjected to screening test & documented by using screening proforma.

INCLUSION CRITERIA:

- Age: 21-45 years
- Married female
- Vaginal smear for Trichomonas vaginalis positive & negative
- Whitish / yellowish discharge per vagina.
- Pruritis Vulva
- Vulval irritation.

- Lower abdominal pain
- Dysuria
- Low back pain
- Patient willing to sign the informed consent.
- Patient who are willing to subject herself for vaginal swab sample collection, as well as to undergo routine laboratory investigation.

EXCLUSION CRITERIA:

- Non specific Leucorrhoea
- Gonorrhoea/ syphilitic infection
- Diabetes mellitus
- Pregnancy/ Lactation
- Fistula/ trauma of genitalia
- Malignancy
- Organic Lesion of Genito-urinary tract
- Hypertension/Any other systemic illness
- Prolapse of uterus
- Bacterial vaginosis
- Vulvovaginal candidiasis

WITHDRAWAL CRITERIA:

- Intolerance to the drug & development of adverse reactions during drug trial.
- Poor patient compliance & defaulters
- Patient turned unwilling to continue in the course of clinical trial.
- Increase in severity of symptoms.

TEST & ASSESSMENTS

- Clinical assessment
- Siddha assessment
- Routine investigation
- Specific investigation.

Clinical Assessment:

- ✓ Whitish or yellowish discharge per vagina
- ✓ Pruritis Vulva
- ✓ Vulval irritation
- ✓ Lower abdominal pain
- ✓ Low back pain

- ✓ Dysuria
- ✓ Dyspareunia

Siddha Assessment:

Siddha way of investigation

Envagai Thervu:

1. Naadi(Pulse perception)
2. Naa(Tongue)
3. Niram(complexion)
4. Vizhi(Eyes)
5. Mozhi(Voice)
6. Sparisam(Palpatory perception)
7. Malam(Bowel habit)
8. Moothiram(Urine)

Neer kuri- Niram, Manam, Nurai, Edai, Enjal.

Neikuri – Vatham, pitham, kabam, thontham, or other fasions.

Routine Blood investigations:

- Hb (gms/dl)
- Total RBC(million/cu.mm)
- Total WBC(million/cu.mm)
- Differential count (%)
  - Polymorphs
  - Lymphocytes
  - Monocytes
  - Eosinophils
  - Basophils
- ESR
- Blood sugar level- fasting(mg/dl) , Postparandial(mg/dl)
- Lipidprofile-Totalcholesterol,HDL(mg/dl),LDL(mg/dl),VLDL(mg/dl)
- VDRL
- Liver function test: Total bilirubin(mg/dl), (direct & indirect),SGOT, SGPT,Alkaline phoaphatase, Total protein(mg/dl), Serum Albumin(mg/dl), Serum globulin(mg/dl), Serum fibrinogen(mg/dl).
- Renal function test: Blood urea (mg/dl), Sr. creatinine(mg/dl).

Urine Examination:

- Albumin
- Sugar (fasting& post parandial)
- Deposits

Vaginal Smear: Wet test for Trichomonas vaginalis

STUDY SUBJECT ENROLLMENT

In this clinical trial, patients reporting at the OPD of Dept of Maruthuvam & Dept of Magalir maruthuvam, Ayothidoss pandithar hospital, National institute of siddha, who satisfies the inclusion and exclusion criteria, will be enrolled for this study.

After ascertaining the patient's willingness, informed consent would be obtained in writing from them in the consent form (Form IV).

The patients who are to be enrolled would be informed (Form V) about the study, trial drug, possible outcome and the objectives of the study in the known language and terms understandable to them.

If the patient give consent to the trial, then the (Form I) screening form should be filled and the ID NO for the patient should be given.

Complete clinical history, complaints and duration, examination findings all would be recorded in the Case record form (Form II). Patient adviced to take blood and urine investigation and the result would be noted in Form III.

Patient would be advised to take the trial drug and appropriate dietary advice would be given according to the patient's perfect understanding.

Conduct of the study:

The day before starting trial drug "Mega rajanga kirutham" purgation will be given with "Meganatha kuligai -1 in ginger juice at early morning". The next day rest will be given to the patients. Third day onwards the trial drug Mega rajanga kirutham -4 ml twice a day before food will be given continuously for 9 days followed by 9 days drug holidays , then 9 days medicine. The patients will be asked to have regular treatment in the OPD once in 9 days. In every visit the clinical assessment f will be recorded in the prescribed Proforma (Form-II). The laboratory investigation will be done before and after treatment and recorded in the prescribed proforma (Form III). For IP patient the drug has been provided & prognosis is noted daily. Routine laboratory investigations & vaginal smear will be done on 0^{th} day and 28^{th} day.

At the end of the trial the patient will be advised to come for follow up for 2 months for observation.

Data management:

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filled in the file. Study NO and patient NO will be entered on the top of file for easy identification. Whenever the study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable forms.
- Screening forms will be filled separately.
- The data recordings will be monitored for completion by guide, (HOD, Dept. of Maruthuvam), SRO (statistics) and the adverse event will be monitored by the members of the phrmacovigilance department of NIS. All forms will be further scrutinized in presence of investigator & Sr. Research officer (statistics) for logical errors and incompleteness of data to avoid any bias. No modification in these results is permitted for unbiased reports.

OUT COME:

The Good outcome is mainly assessed by the vaginal smear when Wet test becomes negative for T. vaginalis and complete relief from clinical symptoms after treatement.

The Moderate outcome is assessed by reduction of clinical symptoms such as white discharge, pruritis vulva, Low back pain and lower abdominal pain.

The Poor outcome is mainly assessed by the vaginal smear when wet test becomes positive for T.vaginalis with clinical symptoms slightly reduced.

STATISTICAL ANALYSIS: Paired t- test for changes in objective parameters.

ASSESSMENT FORMS

FORM I	Screening & selection Proforma
FORM II	Case record form
FORM III	Laboratory investigation form
FORM IV	Drug compliance form
FROM V	Patient information form
FORM VI	Informed Consent form
FORMVII	Withdrawal form/ adverse reaction form (pharmacovigilance form)
FIRM VIII	Dietary advice form

DRUG REVIEW

DRUG REVIEW

1) ATHI PATTAI

Name	: Athi
Botanical Name	: Ficus *racemosa*. Linn.
English Name	: Country fig, Cluster fig, gular fig.
Family	: Moraceae
Synonyms	: Atham, athavu, uthumbaram, koli, supirathashtam.
Part used	: Bark
Taste	: Astringent
Quality	: Coolant
Division	: Sweat
Action	: Astringent
குணம் (character)	: வீறு கடுப்பிரத்தம் வெண்சீத ரத்தமொடு நாறுவிர ணங்களெலாம் நாடாவாம்- கூறுங்கால் அத்திதரு **மேகம்போம்** ஆயிழையே! எஞ்ஞான்றும் அத்திப்பாற் பட்டைக் கறி. –Ref Gunapadam Mooligai vaguppu pg no-21
Activity	: Astringent, Anti inflammatory, Anti oxidant, Hypoglycemic, Anti nocioceptive, Anti bacterial,
Chemical constituents	: β-sitosterol, glanol, lupeol acetate, α- amyrin acetate, tetra cyclic tri terpine gluanol acetic acid, β-sitosterol-D-glucoside and friedellin glycoside β-D- glucosyloxy benzoic acid along with sterols, hydrocarbons, sugars and amino acids.

2) NAVAL PATTAI

Name	: Naval
Botanical Name	: Syzygium *cumini*. Linn.
English Name	: Jambul
Family	: Myrtaceae
Synonyms	: Navval, nambu, sambu, satuvalam, sambal, surabipathirai, Aarugatham, sathavam, neraedu, neraedam.
Part used	: Bark
Taste	: Astringent
Quality	: Coolant
Division	: Pungent
Action	: Astringent
குணம் (character)	: வாத மறுங்கரப்பான் மாறும் விரணமொடு ஓதமுறு நீரிழிவு முந்துரத்த- சீதமுங்காய் மாவன் சுரமும் **வளர்மேகமும் போகும்**

நாவலன் வேரதனை நாடு.

Ref -Gunapadam Mooligai vaguppu pg no-571

Chemical constituents : Myricetin-3-L-arabinoside, dihydromyricetin.

Activity : Astringent, Anti oxidant, Antiinflammatory, Anti bacterial, Anti HIV, Anti fungal, Anti diabetic.

3) OOTHIYAM PATTAI

Name : Oothiyam
Botanical Name : Lannea *coromandelica*. Merr.
English Name : Rhus olina
Family : Anacardiaceae
Synonyms : Uthimaram, moothagam.
Part used : Bark
Taste : Astringent
Quality : Hot
Division : Pungent.
Action : Astringent, Tonic, Anti septic, styptic.
Uses : Bark decoction used for **leucorrhoea** and menorrhagia.

Ref- Gunapadam Mooligai vaguppu pg no-173.

Chemical constituents: Quercetin, Aralia cerebroside, β-sitosterol palmitate, myricadiol, protocatechuic acid, Isovallin, transcinnamic acid, Palmitic acid, stearic acidP hydroxybenzoic acidethyl ester.

Activity : Anti inflammatory, Astringent, Tonic, Disinfectant, and Styptic.

4) KARUMBU RASAM

Name : Karumbu
Botanical Name : Saccharam *officinarum*. Linn.
English Name : Sugar cane, Noble cane
Family : Poaeceae
Synonyms : Punar poosam, ekku, vaei.
Part used : Juice
Taste : Sweat
Quality : Coolant
Division : sweat
Action : Demulcent, antiseptic, coolant, Laxative, Diuretic.

குணம் (character) : கரும்பிரத மெத்தவுண்டாற் காணுங் கபநோய்
விரும்பிவெல்ல மெத்தவுண்டால் **மேகம்** தருமதுநீர்

உண்டாமதைமிதமா யுண்டால்மேகம் பித்தம்
மிண்டாமற் சாந்தமுறும் விள்.

Ref- Gunapadam Mooligai vaguppu pg no- 237.

Chemical constituents : 5-o-Methyl apigenin, 3', 4', 5, 7 tetra hydroxyl-3, 6-dimethoxy flavox.

Activity : Anti inflammatory, Anti thromboitic, Anti hepato toxic, Analgesic, Demulcent, Antiseptic, Cooling, Laxative, Diuretic, Nutrient, Anti oxidant.

5) NELLIKKAI CHARU

Name : Nelli
Botanical Name : Emblica *officinalis*. Linn.
English Name : Indian goose berry
Family : Euphorbiaceae
Synonyms : Amalagam, Aalagam, aambal, aamarigam, thaththari, thaththiri, korangam, miruthupala, meethunthu.
Part used : Juice
Taste : sour, astringent, sweat.
Quality : Coolant
Division : Sweat
Action : Astringent, coolant, diuretic, laxative.
குணம் (Character) : நெல்லிக்காய்க் குப்பித்தம் நீங்கு மதன்புளிப்பால்
செல்லுமே வாதமதிற் சேர்துவரால்-சொல்லுமையம்
ஓடுமிதைச் சித்தத்தில் உன்ன அனலுடனே
கூடுபிற **மேகமும்** போங் கூறு.

- Ref- Gunapadam Mooligai vaguppu pg no-621.

Chemical constituents : Linoleic acid closely related to linseed oil, ellagic acid, lupeol.

Activity : Anti inflammatory, Anti oxidant, Analgesic, Anti-ulcerogenic, Anti diabetic, Anti mutagenic, Hypo lipidemic, Anti coagulant, Anti bacterial, wound healing.

6) ELUMICHAI CHARU

Name : Elumichai
Botanical Name : Citrus *lemon.* Linn.
English Name : Lime
Family : Rutaceae
Part used : Lemon juice
Taste : Sour.

Quality : Hot
Division : Pungent
Action : Coolant.
குணம் (character) : "சதாபலக் கனிகாய சமூலமு முணவே
நிதானமாய் பயித்திய நிந்தையாய் அகலுமே"

எலுமிச்சை பழம், எலுமிச்சை காய், எலுமிச்சை வேர், இலை இவைகளை கொள்ளின் **தீக்குற்றத்தால் உண்டான நோய்களும்,** வெறி நோயும் போம்.
Ref- Gunapadam Mooligai vaguppu pg no-159.

Chemical constituents\ : Hesperidin, Narigin, Poncirin.
Activity : Anti fungal, Anti microbial, Refrigerant, Carminative.

7) GINGELI OIL

Name : Ell
Botanical Name : Sesamum *indicum.* Linn.
English Name : Gingeli oil
Family : Pedaliaceae
Synonyms : Thilam
Part used : Oil
Taste : Sweat
Quality : Hot
Division : Sweat
Action : Coolant, Laxative, tonic, Demulcent, Emollient.

Chemical constituents : Lignans, sesamolin, sesamin, pinoresinol, lariciresinol.
Activity : Anti oxidant, Emmenagogue, Stimulant, Tonic, Diuretic, Galactogogue, Laxative.

8) GHEE

Name : Cow's ghee
Activity : Anti inflammatory, Anti viral, Antioxidant, Tonic.

பசு நெய்யின் குணம்: தாகமுழ லைசுட்கம் வாந்தி பித்தம் வாயுபிர
மேகம் வயிற்றெரிவு விக்கலழல்-மாகாசங்
குன்மம் வறட்சி குடற்புரட்ட லஸ்திசுட்கஞ்
சொன்மூலம் போக்குநிறைத் துப்பு.
Ref- Gunapadam thathu jeeva vaguppu-pg no-702

Uses : Cow's ghee is used for thirst, pitha diseases, vomiting, Poisons, ulcer, Sexually transmitted diseases, hiccough, cough, burning sensation of stomach, Bone diseases, haemorrhoides.

Chemical constituents of Ghee:

It contains approximately 8% saturated fatty acids which make it easily digestible. The digestibility co efficient or the rate of absorption is 96% which is better than any other animal or vegetable fat. It contains triglycerides, di-glycerides, mono-glycerides, phospholipids, beta carotene 600IU and vitamin E which are known anti-oxidants.

9) ELAM

Name : Elam
Botanical Name : Elettaria *cardamomum*. Maton.
English Name : Cardamomum seeds
Family : Zingiberaceae
Synonyms : Aanji, korangam, thudi.
Part used : seed
Taste : Pungent.
Quality : Hot
Division : Pungrent
Action : Stimulant, Carminative, Stomachic
குணம் (character):

தொண்டை வாய்கவுள் தாலுகு தங்களில்
தோன்றும் நோயதி சாரம்பன் **மேகத்தால்**
உண்டை போலெழுங் கட்டி கிரிச்சரம்
.....
ஆல மாங்கமழ் ஏல மருந்ததே.

Ref- Gunapadam Mooligai vaguppu pg no-166.

Chemical constituents: α- Pinene, β- Pinene, Sabinene, myrcene, D- Limonene, 1, 8 Cineole.

Activity : Anti cancer, Immuno modulatory, Stimulant, Carminative, Stomachic.

10) THALISA PATHIRI

Name : Thalisapathiri
Botanical Name : Taxus *buccata*
English Name : flaurtia calaphracta, many spiked flacortia, east Himala fir yans silva.
Family : Taxaceae
Part used : Leaf
Taste : Pungent.
Quality : Hot
Division : Pungrent
Action : Tonic, Carminative, Stomachic, Exopectorant.

Chemical constituents: Taxine, Taxol.

Activity : Anti inflammatory, Anti nocioceptive, Stomachic, Carminative, Expectorant, Tonic.

11) KIRAMBU

Name : Lavangam
Botanical Name : Syzygium *aromaticum*. Linn.
English Name : Cloves
Family : Myrtaceae
Synonyms : Anjugam, urkadam, karuvai kirambu, sosam, thirali, varangam.
Part used : Flowerbud.
Taste : Pungent.
Quality : Hot
Division : Pungrent
Action : Carminative, Anti spasmodic, Stomachic.

Chemical constituents: Caryophyllane, Eugenol, Naphthaene, Eugenine

Activity : Anti fungal, Anti spasmodic, Carminative, Stomachic.

12) SATHIKKAI

Name : Sathikkai
Botanical Name : Myristica *fragrans*. Houtt.
English Name : Nut Meg
Family : Myristicaceae.
Synonyms : Kulakkai,
Part used : Ripe
Taste : Astringent.
Quality : Hot
Division : Pungent
Action : Stimulant, Carminative, Narcotic, Aromatic, Aphrodisiac, Tonic.

Chemical constituents : Seven new dimeric phenyl propanoides, neolignan, erythrosurinamensin and a diaryl phenyl proponoid, virolane.

Activity : Anti inflammatory, Stimulant, Carminative, Narcotic, Aromatic, Aphrodisiac, And Tonic.

13) CHITRARATHAI

Name : Chitrarathi
Botanical Name : Alpinia *officinarum.*Hance.
English Name : Galangal the lesser
Family : Zingiberaceae

Part used : Root
Taste : Pungent.
Quality : Hot
Division : Pungrent
Action : Expectorant, Stomachic, Febrifuge.

Chemical constituents: Galangin, Kaempferide, Kaempferol.

Activity : Anti inflammatory, Anti oxidant, Anti biotic, Anti- ulcer, Expectorant, Stomachic, Febrifuge.

14) ATHIMATHURAM

Name : Athimathuram
Botanical Name : Glycirrhiza *glabra*.Linn.
English Name : Jequitity, Indian or Jamaica Liquorice.
Family : Fabaceae
Synonyms : Athingam, atti mathugam, kunri ver.
Part used : Root
Taste : Sweat,
Quality : Coolant
Division : Sweat.
Action : Febrifuge, Emollient, Demulcent, Expectorant, Laxative, Tonic.
குணம் : புத்திக்கு வித்தாகும் சந்தாபந் தீர்க்கும்
புகைந்தெடுக்கும் சேட்டுமத்தைப் பித்தரோகத்தை
அத்திப் பற்றின **மேகந்தன்னை** வாதத்தினை
யறுத்திடும் வச்சிரம் என்பார் அதிமதுரந்தனையே.

Ref- Gunapadam Mooligai vaguppu- pgno- 14.

Chemical constituents : Glycyrrhizin, Anethole, Iso flavane glabrene, Iso flavane glabridin, Phyto oesrigens.

Activity : Anti inflammatory, Anti oxidant, Emollient, Anti cancer, Anti microbial, Anti viral, Demulcent, Mild Expectorant, Laxative, Tonic, Immuno modulator.

15) NILAPANAI KIZHANGU

Name : Nilapanai kizhangu
Botanical Name : Curculigo *orchioides.* Gaertn.
English Name : Black Musale
Family : Hypoxidaceae.

Synonyms	: Varagi, Musali, Thiralaram, Thiragaththaru, Thiranarasan, Sagiyam, Thalamooli, Thalaithathu, Nilavizhumi, Naeyam, Kuraththi, sithi.
Part used	: Root tuber
Taste	: Sweat.
Quality	: Coolant,
Division	: Sweat.
Action	: Emollient, Laxative, Tonic, Carminative, diuretic, Astringent.
குணம் (character	: மேக வனல்தணியும் வெண்குட்டந் தான்விலகும் போக மிகவுமுறும் பொற்கொடியெ!-போகாத சூலைமேகங் களொடு துன்னுகரும் புள்ளியும்போஞ் சால நிலப்பனைக்குத் தான். Ref- Gunapadam Mooligai vaguppu pg no- 576.
Chemical constituents	: 5.7, dimethoxy-dihydro myrcetin- 3-0-α-L-xylopyranosyl (4-1) B-D glycophyrranoside.
Activity	: Anti cancerous activity, Anti inflammatory, Anti bacterial, Anti oxidant, Emollient, Laxative, Carminative, Tonic, Astringent.

ATHI PATTAI

NAVAL PATTAI

OOTHIYAM PATTAI

ATHIMATHURAM

CITRARATHAI

NILAPANAI KIZHANGU

THALISA PATHIRI

KIRAMBU

SATHIKKAI

ELAM

NELLIKAI CHARU

KARUMBU CHARU

ELUMITCHAI CHARU

THENGAI PAAL

COW'S GHEE

GINGELY OIL

MEGA RAJANGA KIRUTHAM

Dosage: 4 ml, twice a day before food.

RESULTS AND OBSERVATION

RESULTS AND OBSERVATIONS

Results of the study were observed with respect to the following criteria;

1. Sex distribution
2. Age distribution
3. Gunam
4. Paruva kaalam
5. Family history
6. Diet
7. Thinai
8. Socioeconomic status
9. Kaalam
10. Thegi
11. Educational status
12. Body built
13. Habit
14. Occupation
15. Treatment history
16. Derangement of Vatham
17. Derangement of Pitham
18. Derangement of Kabam
19. Derangement of envagai thervugal
20. Neikkuri analysis
21. Derangement of udal thathukal
22. Clinical features distribution
23. Improvement after treatment.

Results and Observation

1. **Sex distribution**: 40 female cases were selected for this dissertation.

2. **Age distributon:**

Age(years)	No of cases	Percentage
21-30	20	50%
31-40	18	45%
41-45	2	5%

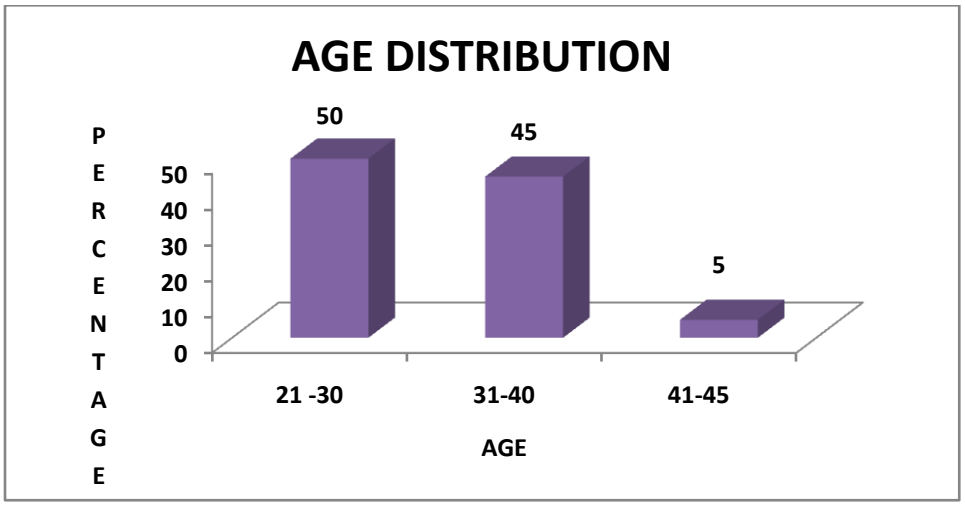


Figure: 1

Observation: Among 40 cases, most of the patients were observed in the age group between 21-30 (50%) and the second most age group was 31-40 (45%).

GUNAM

GUNAM	NO of CASES	PERCENTAGE
Sathuva gunam	0	0
Rastha gunam	40	100%
Thamo gunam	0	0

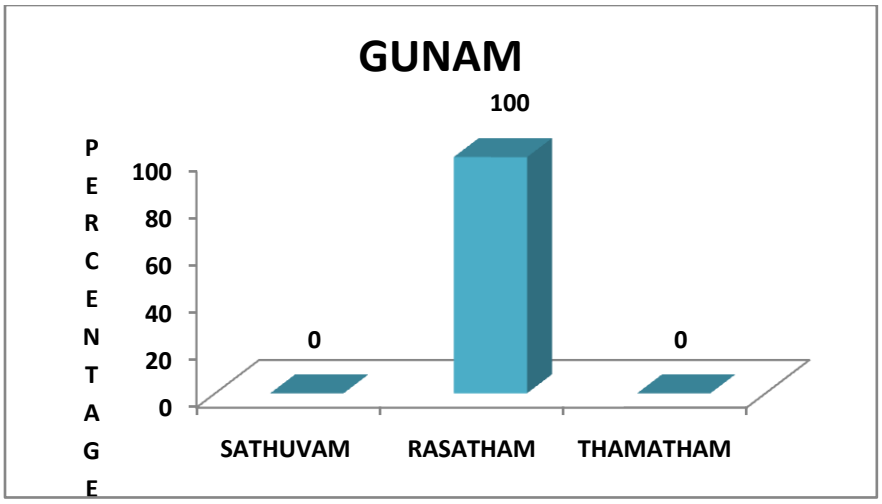


Figure: 2

Observation: All the 40 cases (100%) were found to posses' Rasatha gunam

Food habit:

vegetarian	Non vegetarian
2.5%	97.5%

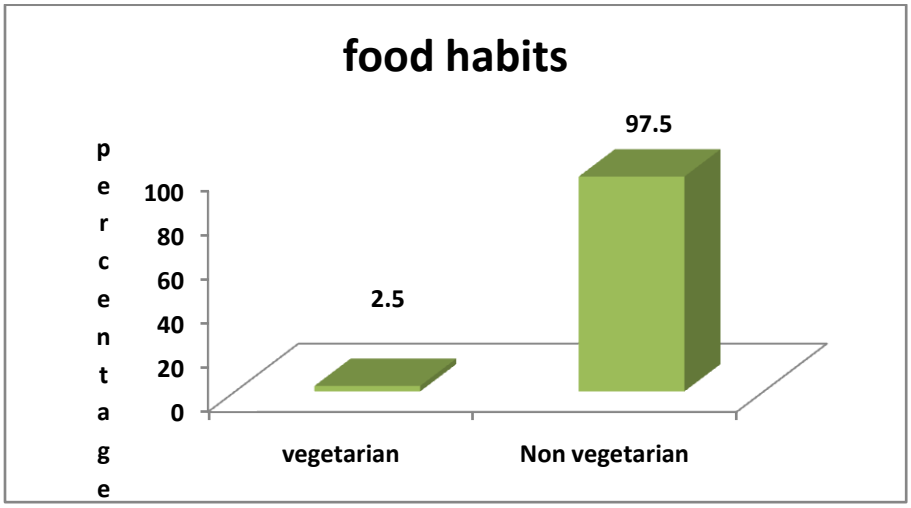


Figure: 3

Observation: Among 40 cases most of the cases were under Non-vegetarian diet.

PARUVA KAALAM (Season):

Season	NO of Cases	Percentage
1. Kaarkaalam	0	0
2. Koothir kaalam	0	0
3. Munpani kaalam	26	65%
4. Pinpani kaalam	14	35%
5. Ilavenil kaalam	0	0
6. Muthu venil kaalam	0	0

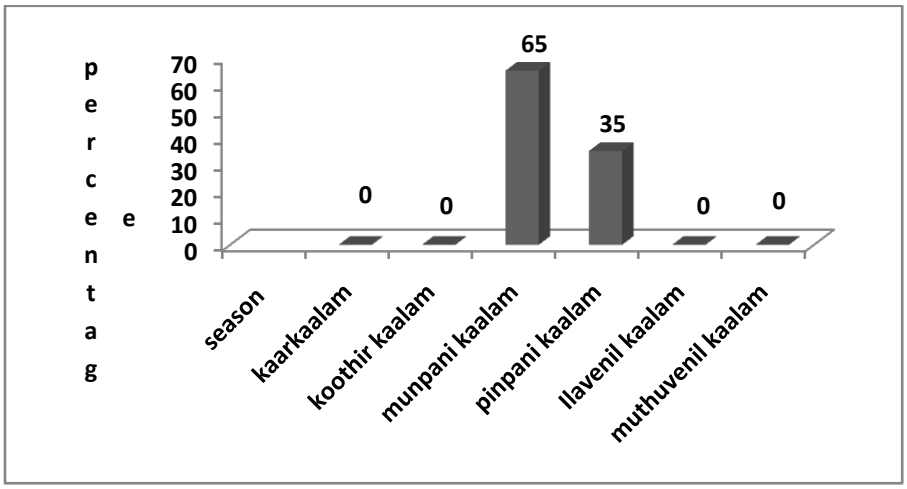


Figure: 4

Observation: Among the 40 patients, 65% were suffered in Munpani kaalam and 35% in Pinpanikaalam.

Family History:

Family history	No of patients	Percentage
Present	4	10
Absent	36	90

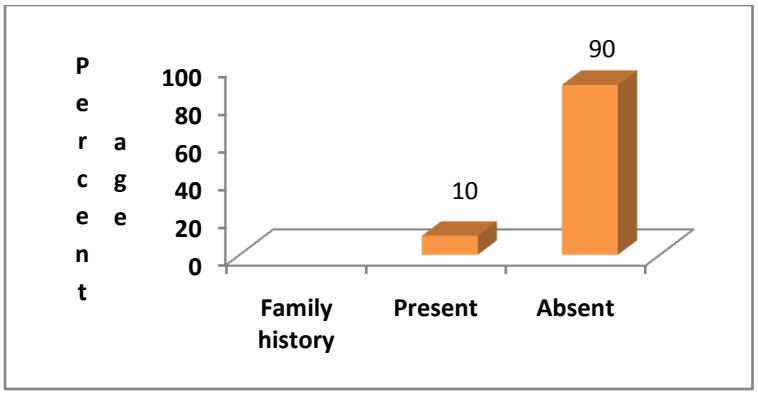


Figure: 5

Observation:

Among 40 cases only 10 % of cases had Family history of vellai noi.

Socio economic status:

Socio economic status	No of patients	Percentage
Low	19	47.5
Middle	16	40
High	5	12.5

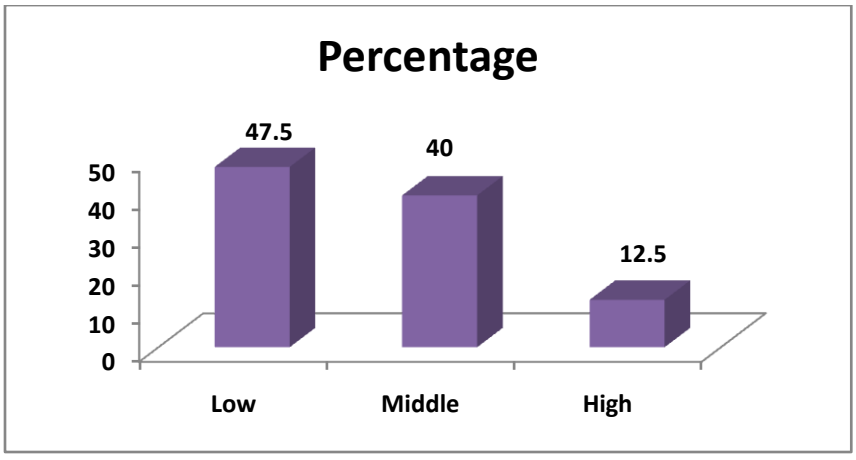


Figure: 6

Observation: Among 40 patients 47.5% were poor, and 40% were middle, and only 12.5% were had high socio- economic status.

THINAI:

Thinai	No of patients	Percentage
Kurinji	1	2.5
Mulli	0	0
Marutham	10	25
Neithal	29	72.5
Palai	0	0

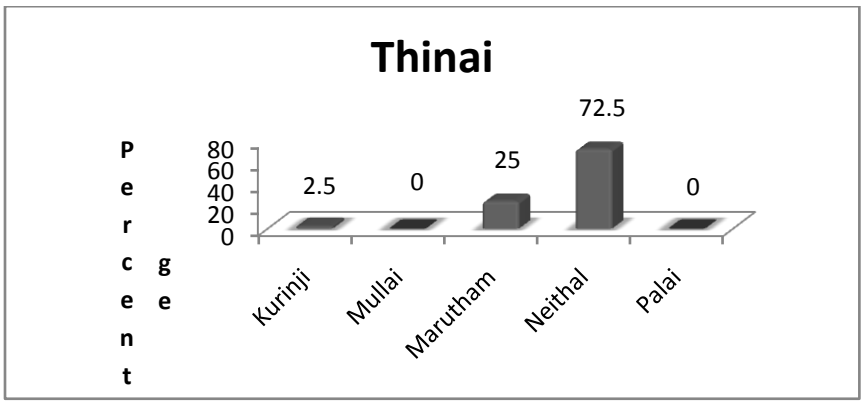


Figure: 7

Observation:

72.5% 0f patients were belongs to Neithal nilam.

25% of patients were belongs to Marutha nilam.

2.5 % of patients were beongs to Kurinji nilam

Kaalam distribution:

Kaalam	No of cases	Percentage
Vatha kaalam	29	72.5
Pitha kaalam	11	27.5
Kaba kaalam	0	0

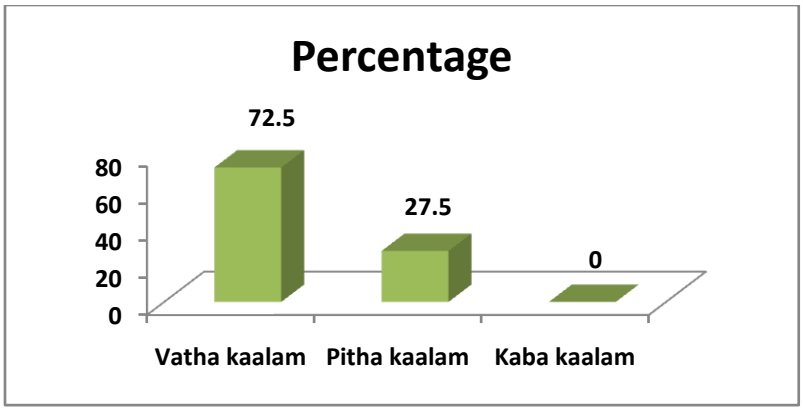


Figure: 8

Observation:

Among 40 cases, 72.5% of cases were in vaatha kaalam (age up to 33 years).

27.5% of cases were in Pitha kaalam (age from 34 to 66 years).

Habit:

All the 40 cases do not have any bad habits, like pan, snuff etc.

Thegi:

Thegi	No of cases	Percentage
Vaatha thegi	12	30
Pitha thegi	15	37.5
Kaba thegi	0	0
Thontha thegi	13	32.5

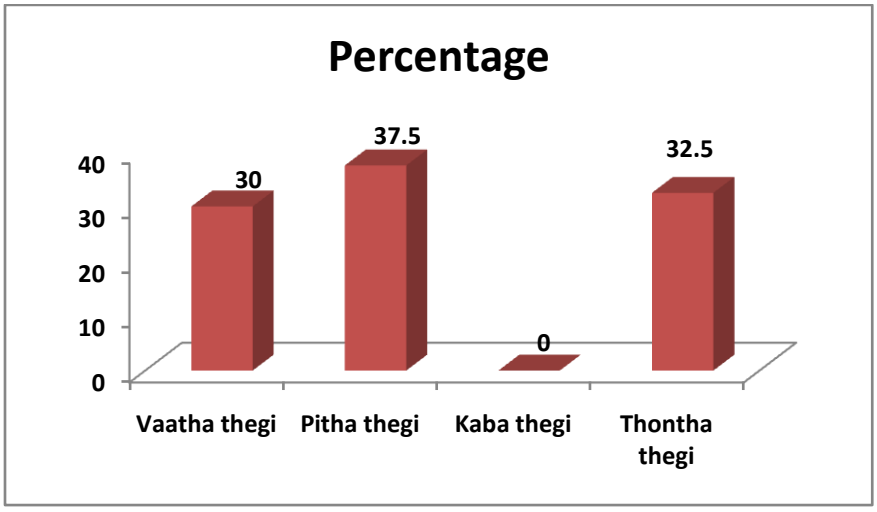


Figure: 9

Observation:

Among 40 cases, 37.5% of patients were Pitha thegi. 32.5% of patients were Thontha thegi. And 30% of patients were Vaatha thegi.

Educational status:

	Literate			Illiterate
	Middle school completed	**High school completed**	**Degree holder**	
No of cases	11	8	5	16
Percentage	27.5	20	12.5	40

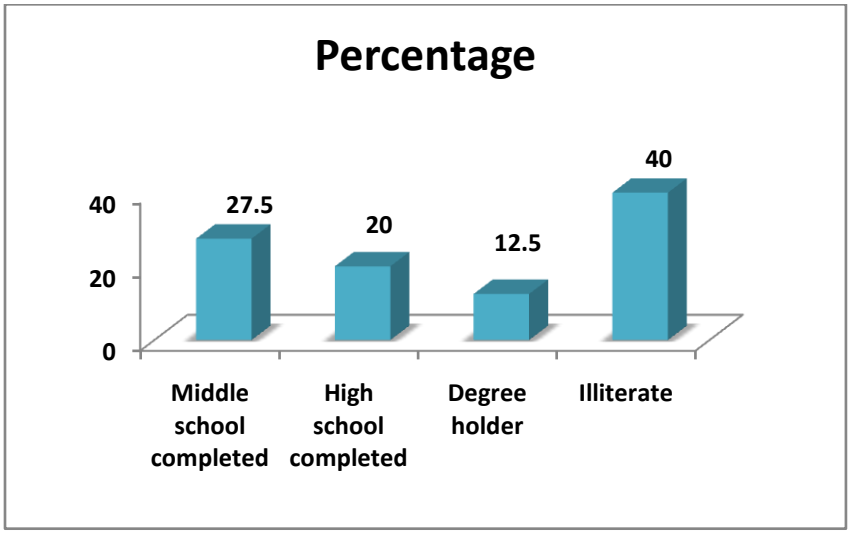


Figure: 10

Observation:

Among 40 cases, 40% of cases were illiterate, 27.5% of patients were middle school completed, and 20% of patients were High school completed. Only 12.5% of patients were degree holder.

Body built:

Body built	**No of cases**	**Percentage**
Lean	22	55
Moderate	11	27.5
Obesity	7	17.5

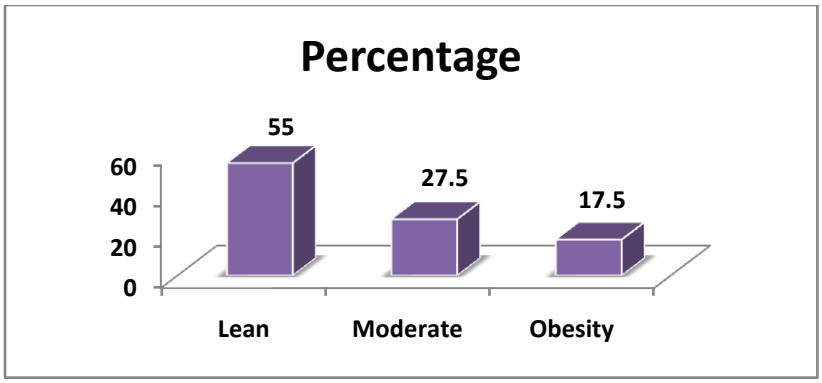


Figure: 11

Observation:

Among 40 cases, 55% of patients were under weight. 27.5% were Normal weight and 17.5% were Obese.

Occupation:

Occupation	No of cases	Percentage
House wives	15	37.5
Sedentary work	5	12.5
Daily wages	20	50

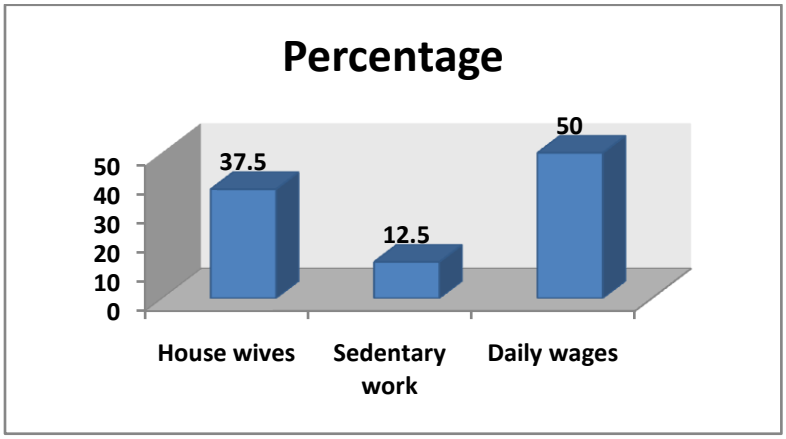


Figure: 12

Observation:

Among 40 cases, 50% of patients are doing field work. 37.5% of patients are housewives. Only 12.5% of patients are doing sedentary work

Treatment history:

Treatment history	No of cases	Percentage
Allopathy	18	45
Sidhha	7	17.5
Ayurvedha	3	7.5
Homeopathy	4	10
No treatment history	8	20

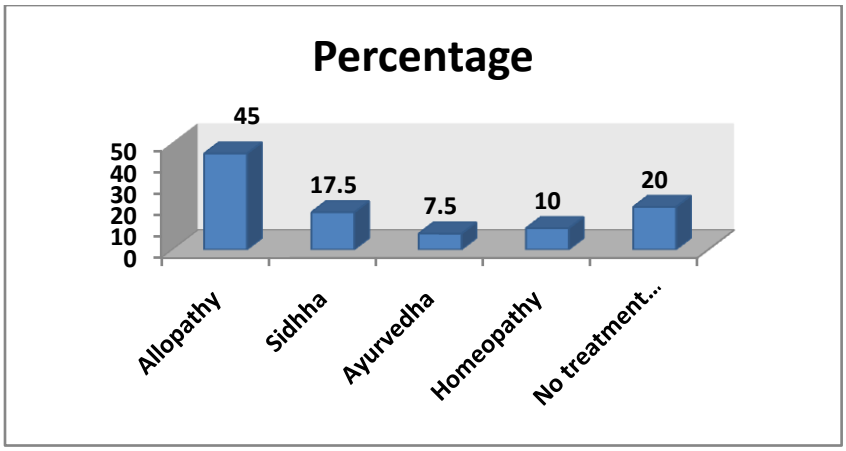


Figure: 13

Observation:

Among 40 cases, 45% of patients had allopathic treatment for leucorrhoea. 20% of patient's dose not had any treatment. 17.5% of patients had siddha treatment, 7.5% had Ayurvedhic and 10% had Homeopathic treatment for the same illness.

Disturbances of Vatham:

Disturbances of vatham	Before Treatment (%)	After Treatment (%)
Piranan	0	0
Abanan	100	20
Uthanan	0	0
Viyanan	100	12.5
Samanan	100	25
Nagan	0	0
Koorman	5	5

Kirugaran	0	0
Devathathan	100	2.5
Dananjeyan	0	0

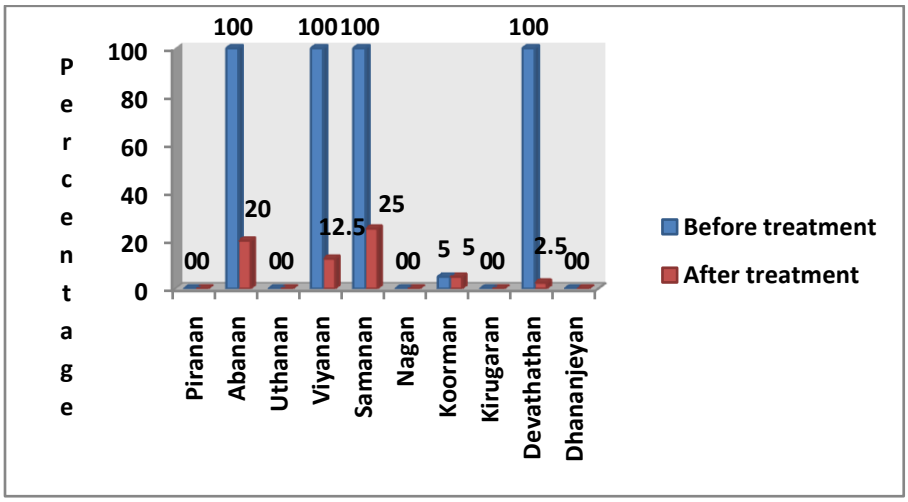


Figure: 14

Observation:

Among 40 cases, before treatment, 100% of patients were affected with Abanan, Viyanan, Samanan and Devathathan. After treatment the abanan was affected in 20%, Viyanan was affected in 12.5%, Samanan was affected in 25%, and devathathan was affected only in 2.5% of patients.

Disturbances of Pitham:

Disturbances of pitham	**Before treatment (%)**	**After treatment (%)**
Anarpitham	50	10
Ranjaga pitham	20	20
Sathaga pitham	0	0
Pirasaga pitham	0	0
Alosaga pitham	5	5

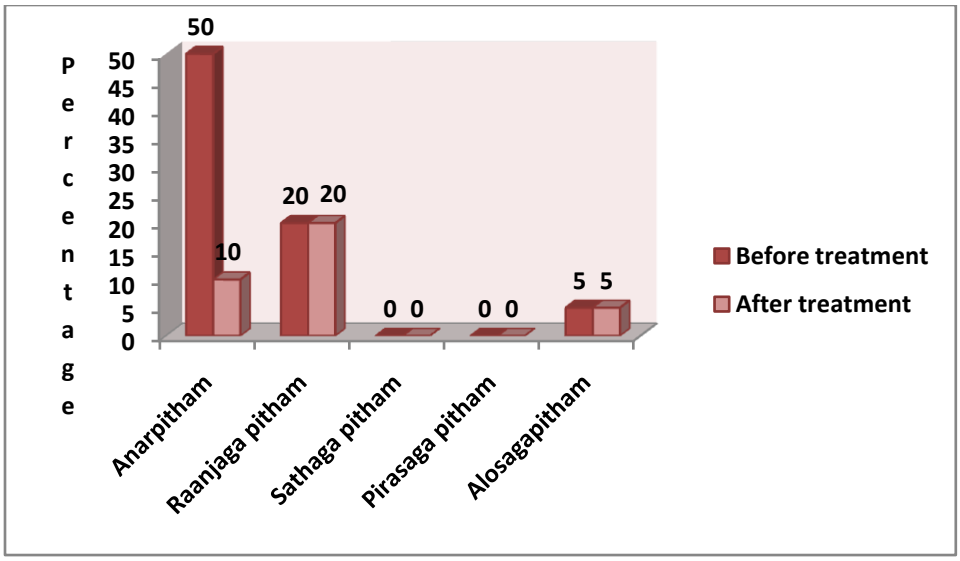


Figure: 15

Observation:

Among 40 cases, 50% of patients were affected Anarpitham in before treatment, and it was affected only in 10% in after treatment.

Disturbances of Kabam:

Disturbances of Kabam	**Before treatment (%)**	**After treatment (%)**
Avalambagam	100	20
Kilethagam	0	0
Pothagam	0	0
Tharpagam	0	0
Santhigam	100	20

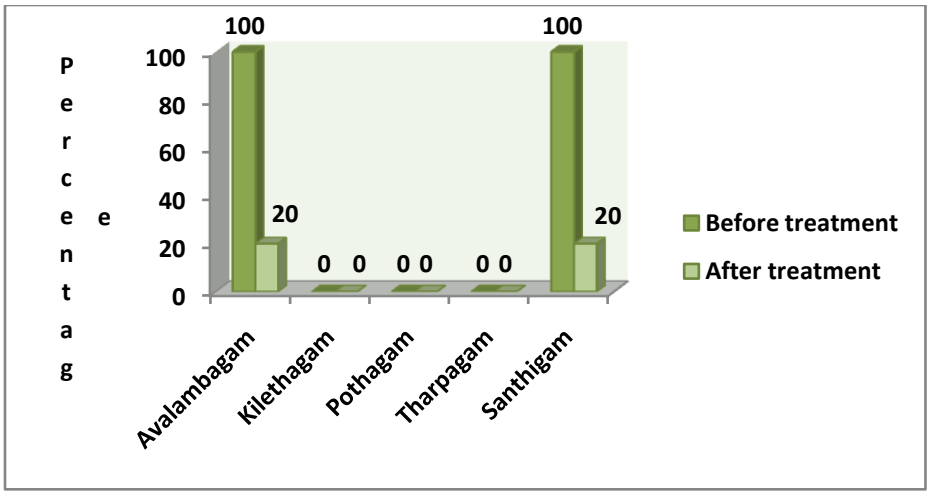


Figure: 16

Observation:

Among 40 cases, 100% of patients were affected with Avalambagam and santhigam in before treatment and after treatment; both were affected only in 20% of patients.

Changes in Kosangal:

Kosangal	**Before treatment (%)**	**After treatment (%)**
Annamaya Kosam	100	20
Piranamaya kosam	80	7.5
Manomaya kosam	100	7.5
Vingnanamaya kosam	5	2.5
Ananthamaya kosam	55	0

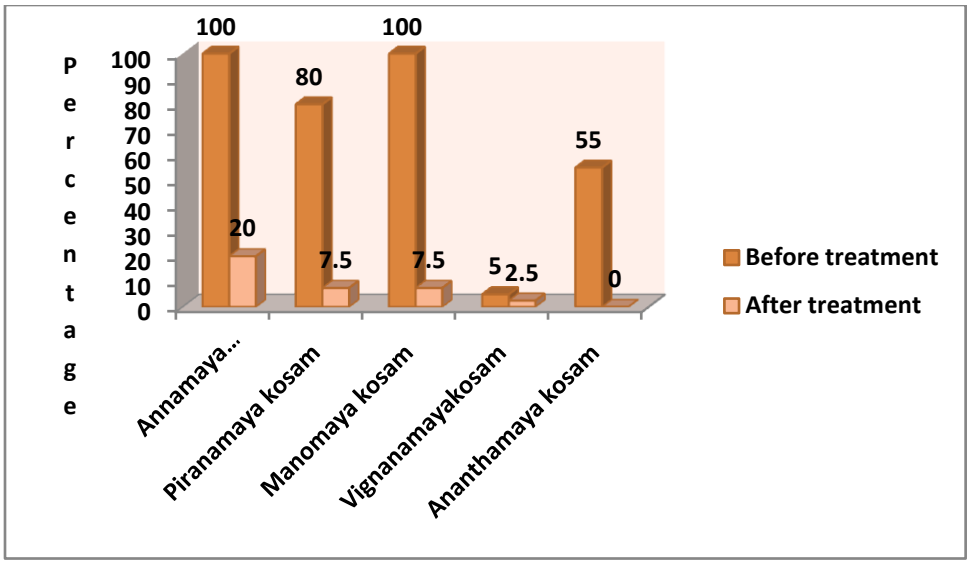


Figure: 17

Observation:

Among 40 cases, 100% of cases were affected with Annamaya kosam in before treatment, and after treatment, it was affected only in 20%of patients.

Among 40 cases, 80% of cases were affected with Piranamaya kosam in before treatment, and after treatment, it was affected only in 7.5% of patients.

Among 40 cases, 100% of cases were affected with Manomaya kosam in before treatment, and after treatment, it was affected only in 7.5% of patients.

Among 40 cases, only 5% of cases were affected with Vignanamaya kosam in before treatment, and after treatment, it was affected only in 2.5% of patients.

Among 40 cases, 55% of cases were affected with Ananthamaya kosam in before treatment, and after treatment, the Ananthamaya kosam was Normal in all 40 cases.

Changes in Udal thathukkal:

Udal thathukkal	Before treatment (%)	After treatment (%)
Saaram	100	5
Senneer	20	20
Oon	0	0
Kozhuppu	0	0
Enbu	30	2.5
Moolai	0	0
Suronitham	100	22.5

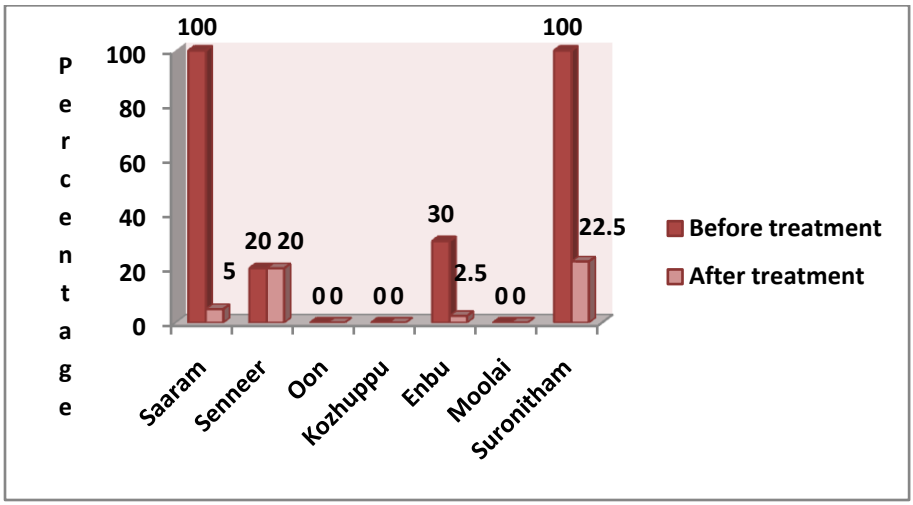


Figure: 18

Observation:

Among 40cases, 100% of cases were affected with Saaram and after treatment it was reduced in to 5%.

Among 40 cases, 100%of cases were affected with Suronitham and it was reduced into 22.5%.

Among 40 cases, 20% of patients were affected with senneer in before and after treatment.

Among 40 cases, 30% of patients were affected with Enbu in before treatment. And it was affected only in 2.5% of cases.

Improvement of signs and symptoms:

Clinical symptoms	Before treatment (%)	After treatment (%)
Profuse, thin, creamy whitish / yellowish discharge per vagina.	100	37.5
Pruritus vulva	97.5	17.5
Vulval irritation	100	10
Dysuria	75	12.5
Abdominal pain	95	37.5
Low back pain	100	42.8
Dyspareunia	100	-

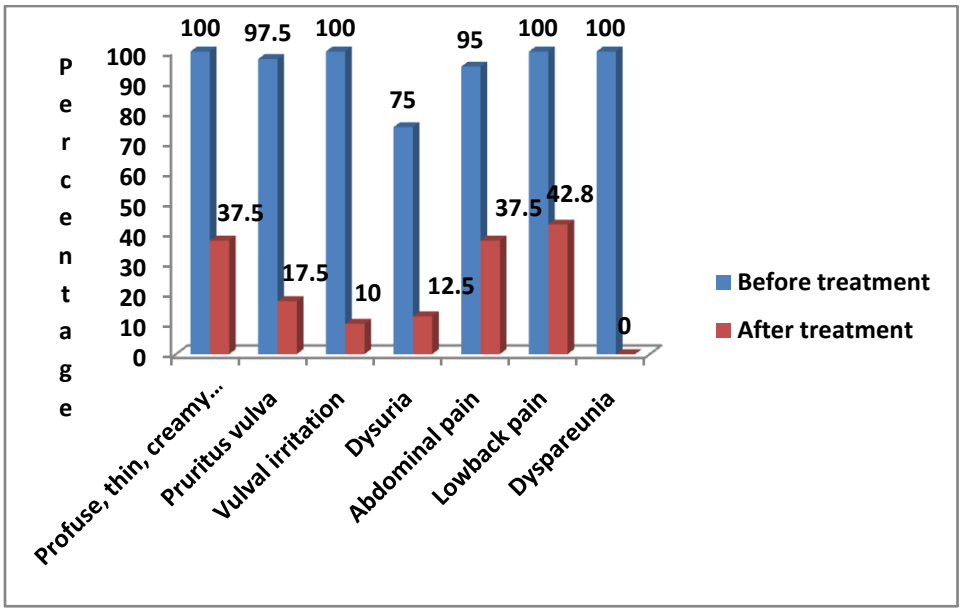


Figure: 19

Observation:

Among 40 cases, 100% of patients had Profuse thin or thick, whitish or yellowish discharge per vagina, and after treatment the above symptoms were present only in 37.5% of patients.

Among 40 cases, 97.5% of patients had Pruritus vulva in before treatment, and after treatment it was present only in 17.5% of cases.

Among 40 cases, 100% of patients had Vulval irritation in before treatment, and after treatment it was present only in 10% of cases.

Among 40 cases, Dysuria was present in 75% of cases in before treatment and after treatment it was present only in 12.5% of cases.

Among 40 cases, abdominal pain was present in 95% of patients, and after treatment it was present in 37.5% of patients.

Among 40 cases, Low back pain and Dyspareunia was present in 100% of cases, and after treatment low back pain was present in 42.5% of cases. Dyspareunia is not elicited due to Itcha pathiyam.

WET test positive for Trichomonas vaginalis

WET test	**NO of cases**	**Before treatment (%)**	**After treatment (%)**
Positive	15	37.5	12.5
Negative	25	62.5	87.5

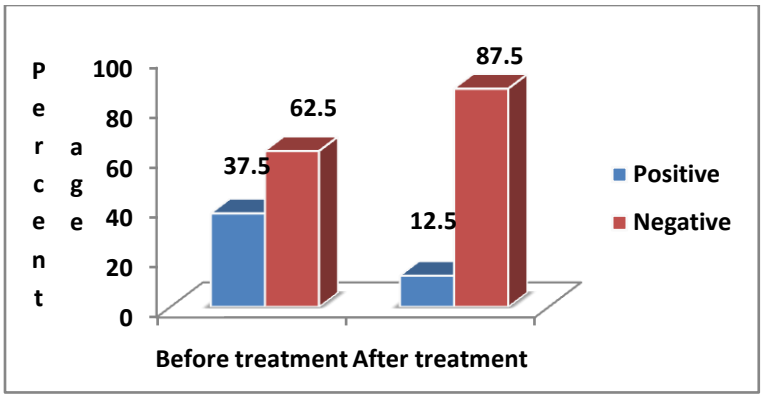


Figure: 20

Observation: Among 15 Wet test positive cases, 10 cases were negative in after treatment i.e. 66% of cases were negative in after treatment.

RESULTS:

Improvement after treatment	**GOOD**	**MODERATE**	**POOR**
	50%	40%	10%

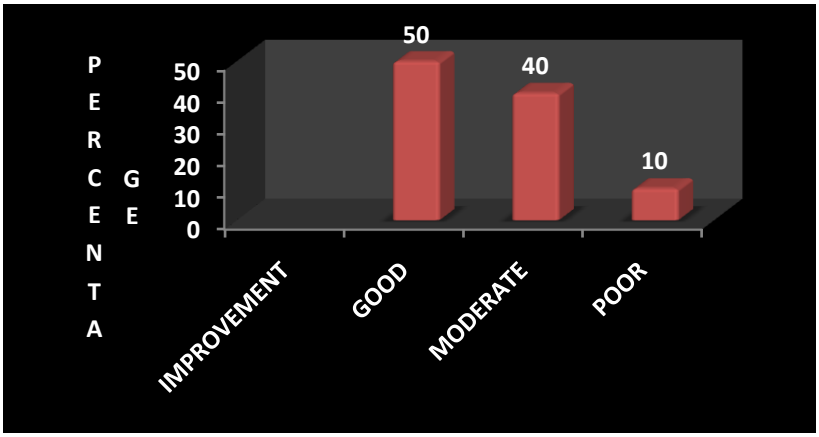


Figure: 21

Observation:

50% of patients showed good result, 40% showed moderate result and only 10% showed poor prognosis.

Results of Pharmacological study:

1) **In vitro anti inflammatory activity by protein (albumin) denaturation assay** :

The test drug Mega rajanga kirutham was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 69.54% was observed at 500 µg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 89.22 % at the concentration of 100µg/ml

2) Anti microbial activity by Disc diffusion method:

The trial drug Mega rajanga kirutham was effective aginst *Trichomonas vaginalis, Staphylococcus aureus, E.coli, Candida albicans* and not active against *Aspergillus niger*.

3) Anti oxidant activity by using DPPH(2,2-Diphenyl 1-2 picrylhydrazyl Assay, Nitric Oxide Radical Scavenging Assay and ABTS assay:

From the results of the present investigation it was concluded that the siddha formulation Mega rajanga kirutham has promising anti-oxidant activity in the estimated test.

4) Physico-chemical evaluation:

Parameter	**Observation**
Color	Yellowish
Smell	Characteristic
Touch	Greasy
Appearance	Turbid

S.No	**Parameter**	**Mean(n=3) SD**
1.	Loss on Drying at 105ºc(%)	8.03±1.09
2.	Total Ash(%)	0.788±0.37

S.No	**Specific test**	**Mega rajanga kirutham**
1.	pH	6

2.	Refractive index	1.48
3.	Iodine value(mg12/g)	101
4.	Saponification value(mg of KOH to saponify 1 gm of fat)	205

5) Phytochemical analysis:

In this evaluation Flavonoids, Steroids, Sugar, Triterepnoids, Coumarins, Phenols, and Proteins are identified.

6) Quantitative estimation of phytoconstituents of Mega rajanga kirutham:

Phyto-constituents	**Mega rajanga kirutham**
Total phenols (GAE mg/gm)	0.934±0.04
Total flavanoids (Quercetin mg/gm)	2.82±0.42

Mean with 3 replicates±SD

7) GCMS Analysis of Mega rajanga kirutham:

19 components were detected inthis analysis. They are following;

1) Oxiranemethanol, 3-propyl-c1s-$$ (3-Propyl-2-oxiranyl) methanol #$$ (3-propyl-2-oxiranyl) methanol $$.
2) 1, 5-Anhydro-6-deoxyhexo-2, 3 Diulose $$ 4H-pyran-4-ON, 2-3 dihydro-3, 5-dihydrxy-6-methyl.
3) Benzofuran, 2, 3-dihydro-$$ 2, 3 Dihydrobenzofuran $$2, 3-dihydro-1-benzofuran # $$ 1- benzofuran $$23-D.
4) 4-Hepten-3-one, methyl, $$ (4f)-4-methyl, 4-hepten-3-one # $$ 1-Benzofuran $$ 23-D.
5) 2-furancarboxaldehyde, 5-(hydrxymethyl)-$$2=furaldehyde, 5-(hydroxymethyl)-$$2-furadehyde-5.
6) Ethyl4-amino-1H-imidazole, 5-carboxylate=$$ 1H-imidazole, 5-carboxylate=$$ 1H-imidazole4-carboxylic acid, 5-amino, ethyl ester $$E.

7) 2-Nonenal, 2-phenyl, $$2-pentylon-2-enal$$(2z)-2-pentyl, 2-nonenal#$$(2z)-2-pentyl-2-nonenal $$(2z)-2p.
8) 2, 4-Diisopropenyl-1-methyl-1-vinylcyclohexane $$ beta-etemen-(2).
9) 8,11,14 Eicosatrienoic acid, (z, z, z)-$$(8E,11E,14E)-8,11,14-icosatrienoic acid# $$(8E,11E,14E)-8,11,14-icosatrienol.
10) 1-Naphthalenol, Decahydro, (1-alpha, 4A, beta-8A alpha) - $$-1-Naphthal, 1, alpha-2, 3, 4, 4A-Alpha-5, 6, 7, 8, 8A, BE.
11) 2H-pyran, 2-(7-heptodecynyloxy) tetrahydro-$$2-(7-heptadecynyloxy) tetra hydro-2-H-pyran# $$ 2(hepta].
12) Cyclooctanol $$cyclooctyl alcohol $$EINECS 211-800-6$$ NSC 60162.
13) 2, 4- Ditert-butylphenol $$2, 4-ditert-butylphenol.
14) 9- Octadecenoic acid (z)-$$ octadec-9-Enioc acid $$(9E)-9-octadecenoic acid # $$(9E)-9-octadecenoic acid.
15) 2-Aminobenzoyl fluride $$2-amino-benzoyl fluride.
16) 1, 2- Benzenedicarboxylic acid, 3-nitro-$$3- Nitrophthalic acid $$ A13-02074$$ AIDS-019415$$ Einecs 210-030-8$.
17) 9- Octadecenoic acid (z)-$$ octadec-9-Enoic acid $$(9E) -9-Octadecenoic aciod # $$ (9E)-9-Octadecenoic acid.
18) Hexanedioic acid, BIS (2-Ethylhexyl) Ester $$ Hexanedioic acid, dioctyl ester $$ adipic acid BIS (2-ethylhe)
19) 9, 12-Octadecadienoic acid (z, z) –$$(9E, 12E)-9, 12-octadecadienoic acid # $$(9E, !@E)-9, 12-octadecadienoic acid.

8) TLC and HPTLC analysis: Peak Table of HPTLC finger printing of MRK

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.34	6.0	0.37	37.3	28.62	0.41	0.6	891.4	17.19
2	0.42	1.3	0.46	25.4	19.55	0.50	6.9	749.1	14.44
3	0.53	8.7	0.61	67.5	51.83	0.68	4.2	3546.3	68.37

INVESTIGATION REPORT

BLOOD INVESTIGATION (Haematology)

S. NO	OP NO	NAME	A/S	TC Cells/cumm		DC (%)							
						P	P	L	L	M	M	E	E
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I28105	B.Anjali	38/f	11800	5500	77	62	19	31	2	3	2	4
2	I04794	A.Ramadevi	38/f	7700	7000	60	57	34	36	3	3	3	4
3	G70637	S.Sasikala	29/f	10900	8100	68	70	29	28	0	0	3	2
4	I38185	S.Saritha	30/f	13100	8900	60	45	28	33	2	2	10	20
5	I44538	P.Anjala	31/f	5600	5500	53	50	41	44	3	3	3	3
6	I41415	A.Suseela	30/f	9300	8900	69	60	26	30	3	5	2	5
7	I1860	M.Jayasree	35/f	5600	7200	62	65	33	30	2	3	2	3
8	I31972	V.Shema	30/f	4600	5600	52	50	44	42	0	4	4	4
9	I34742	S.Radhika	30/f	6500	6600	60	69	35	29	0	0	5	2
10	I37025	B.Jeyalakshmi	34/f	8200	7900	54	55	41	40	0	0	5	5
11	I46385	S.Sridevi	21/f	5200	4700	58	65	35	30	0	0	7	5
12	I41931	Lakshmi	37/f	7700	6900	61	58	30	31	5	3	4	8
13	I29619	N.Mythili	30/f	7100	7800	58	60	36	35	3	2	3	5
14	I35655	Vijayasree	30/f	9100	9400	65	63	30	32	0	0	5	5
15	I50296	Vijayalakshmi	26/f	6000	5700	51	50	43	44	3	3	3	3
16	I24039	L.Vijaya	32/f	4600	5400	62	58	31	35	0	0	7	7
17	I31958	K.Srimathy	32/f	8000	8300	56	55	40	40	2	2	2	3
18	I56390	M.Selvi	27/f	5000	4400	56	50	37	44	3	3	4	3
19	I36211	V.Valliamma	32/f	9500	8500	45	63	35	21	1	5	19	11
20	I28243	M.Kujila	30/f	7600	6600	42	33	44	55	1	2	13	10
21	I36215	B.Rose	32/f	5500	4800	48	54	48	42	2	2	2	2
22	I58375	P.Amara	24/f	8500	8100	59	51	33	39	4	2	4	8
23	I36214	S.Vasantha	45/f	6300	4700	52	52	34	38	3	2	11	8
24	I50527	V.Amuthini	27/f	9200	9200	59	51	33	44	3	3	3	2
25	I55449	Rathanavathy	31/f	6100	8500	60	69	35	28	3	2	2	1
26	I54714	J.Anitha	29/f	8800	8200	65	60	30	38	3	1	2	1

27	I43262	Rajeswari	31/f	5700	6800	52	55	43	41	3	1	2	2
28	I60109	M.Vimala	30/f	5600	6200	50	52	46	44	2	2	2	2
29	I53755	G.Ammatchi	36/f	10200	9200	60	60	36	38	0	0	4	2
30	F82273	V.Jayasree	33/f	10100	9800	50	55	45	40	3	3	2	2

S. NO	**OP NO**	**NAME**	**A/S**	**TC**		**DC**							
						P	P	L	L	M	M	E	E
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
31	H66126	S.Shanthi	31/f	9800	9200	70	70	23	28	3	1	4	1
32	I48333	S.Bridgetmary	45/f	10300	9200	55	50	41	43	2	4	2	3
33	I47675	Suganthi.N	27/f	8900	8500	60	50	31	41	0	1	9	8
34	G39746	H.Gomathi	37/f	4700	5800	40	40	53	51	1	0	7	8
35	I00923	G.Yuvarani	35/f	8700	8800	60	56	35	41	0	0	5	3
36	I66325	L.Manju	27/f	7300	5000	54	35	34	60	4	0	8	5
37	H96938	J.Maheswari	27/f	6400	5500	50	55	39	38	1	0	10	7
38	II68998	K.Prasanna	32/f	7200	7600	49	58	44	37	0	0	7	5
39	I60605	G.kala	26/f	6700	7000	61	60	35	38	0	0	4	2
40	I63726	A.Manimegalai	22/f	9300	8700	60	56	34	36	3	3	3	5

S. NO	**OP NO**	**NAME**	**A/S**	**ESR mm/1 hr**		**Hb gm/dl**		**Bldsug(F) mgs%**		**Bldsug(PP) mgs%**		**VDRL**	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I28105	B.Anjali	38/f	52	24	12.8	13.3	110	107	120	99	NR	NR
2	I04794	Ramadevi	38/f	22	22	10.1	9.8	76	102	82	112	NR	NR
3	G70637	Sasikala	29/f	22	12	13.8	13	99	97	120	110	NR	NR
4	I38185	Saritha	30/f	16	12	13.9	13.9	58	81	110	126	NR	NR
5	I44538	Anjala	31/f	4	26	12.7	12.8	63	92	110	120	NR	NR
6	I41415	Suseela	30/f	16	28	10	10.6	77	94	110	134	NR	NR
7	I01860	Jayashree	35/f	34	42	9.5	10.2	110	78	128	128	NR	NR
8	I31972	Shema	30/f	8	40	12.9	13.5	60	85	101	91	NR	NR

9	I34742	Radhika	30/f	12	4	13.7	13.3	65	97	128	124	NR	NR
10	I37025	Jeyalakshmi	34/f	28	6	8.7	8.8	79	103	112	112	NR	NR
11	I48385	Sridevi	21/f	12	12	13.3	14	75	104	76	84	NR	NR
12	I41931	Lakshmi	37/f	12	8	13.6	12.6	72	99	98	118	NR	NR
13	I29619	Mythili	30/f	18	44	12.3	13	73	100	108	154	NR	NR
14	I35655	Vijaya	30/f	8	36	12.5	12.7	87	110	108	117	NR	NR
15	I50296	Vijayalakshmi	26/f	8	6	12.3	13.3	62	99	50	102	NR	NR
16	I24039	Vijaya	32/f	32	16	11.3	11.4	82	106	81	140	NR	NR
17	I31958	Srimathy	32/f	8	16	13.8	13.9	92	97	111	115	NR	NR
18	I56930	Selvi	27/f	8	6	11.9	11.2	92	97	82	102	NR	NR
19	I36211	Valliamma	32/f	18	22	12.5	12.6	92	94	110	120	NR	NR
20	I28243	Kujila	30/f	20	6	12.8	12.7	83	95	102	108	NR	NR
21	I3245	Rose.B	32/f	16	6	13.1	12.5	84	110	112	122	NR	NR
22	I58375	Amara.p	24/f	12	4	11.3	11.5	83	94	112	120	NR	NR
23	I36214	Vasantha	45/f	42	32	6.5	5.9	94	90	110	110	NR	NR
24	I50527	Amuthini	27/f	42	12	12.8	12.8	87	86	138	101	NR	NR
25	I55449	Rathnavathy	31/f	22	40	11.1	11.3	97	105	88	90	NR	NR
26	I54714	Anitha	29/f	24	6	9	9.2	99	110	117	125	NR	NR
27	I43262	Rajeswari	31/f	8	4	11.5	11.9	101	87	124	110	NR	NR
28	I60109	Vimala	30/f	46	18	13.9	13.9	124	110	95	120	NR	NR
29	I53755	Ammatchi	36/f	12	8	12.7	12.6	110	105	127	115	NR	NR
30	F82273	Jayasree	33/f	12	6	14.6	14.2	100	110	150	128	NR	NR
31	H66126	Shanthi	31/f	62	8	13	13.2	88	92	110	120	NR	NR
32	I48333	Bridjetmary	45/f	110	50	10.5	10.2	107	100	142	115	NR	NR
33	I47675	Suganthi	27/f	34	32	13.1	12.8	107	84	106	91	NR	NR
34	G39746	Gomathi	37/f	12	22	8.6	8.3	92	86	93	95	NR	NR
35	I00923	Yuvarani	35/f	42	10	13.3	12.8	104	84	133	120	NR	NR
36	I66325	Manju	27/f	22	42	11.6	11	111	103	111	93	NR	NR
37	H96938	Maheswari	27/f	40	70	12.5	11.6	100	89	131	98	NR	NR
38	I68998	K.Prasanna	32/f	32	20	13.2	12.2	97	83	110	94	NR	NR
39	I50605	G.kala	26/f	34	12	13	13.2	94	84	107	93	NR	NR
40	I63726	Manimegalai	22/f	4	6	12.5	12.7	104	110	135	127	NR	NR

S. NO	OP NO	NAME	A/S	Liver function test(mg/dl)													
				T.bilirubin (mg/dl)		Dir mg/dl		Ind mg/dl		SGOT Iu/l		SGPT Iu/l		ALK phos Iu/l		Total Protein g/dl	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I28105	B.Anjali	38/f	0.3	0.3	0.1	0.2	0.2	0.1	14	15	11	09	51	40	7.0	6.6
2	I04794	A.Ramadevi	38/f	0.3	0.4	0.1	0.1	0.2	0.3	22	20	12	13	56	58	7.4	7.1
3	G70637	S.Saaikala	29/f	0.5	0.5	0.2	0.2	0.3	0.3	29	14	42	17	97	95	7.6	7.0
4	I38185	S.Saritha	30/f	0.5	0.5	0.2	0.2	0.3	0.3	18	17	15	18	48	35	7.0	6.8
5	I44538	P.Anjala	31/f	0.6	0.7	0.3	0.3	0.3	0.4	25	23	17	18	48	47	7.9	7.0
6	I41415	A.Suseela	30/f	0.2	0.4	0.1	0.2	0.1	0.2	22	21	11	14	70	65	7.2	7.4
7	I1860	M.Jayasree	35/f	0.2	0.3	0.1	0.1	0.1	0.2	16	24	11	18	51	47	7.4	7.8
8	I31972	V.Shema	30/f	0.8	0.8	0.4	0.4	0.4	0.4	22	20	24	24	59	61	6.7	7.1
9	I34742	S.Radhika	30/f	0.4	0.7	0.2	0.3	0.2	0.4	14	11	10	10	30	27	6.9	6.5
10	I37025	B.Jeyalakshmi	34/f	0.5	0.7	0.2	0.3	0.3	0.4	13	07	11	13	84	66	6.7	6.8
11	I46385	S.Sridevi	21/f	0.3	0.4	0.1	0.2	0.2	0.2	15	16	16	16	49	61	7.2	7.1
12	I41931	Lakshmi	37/f	0.9	0.9	0.3	0.4	0.6	0.5	15	13	10	06	58	55	7.7	7.2
13	I29619	N.Mythili	30/f	0.6	0.8	0.2	0.3	0.4	0.5	20	17	17	13	48	52	7.4	7.3
14	I35655	Vijayasree	30/f	0.4	0.3	0.2	0.2	0.2	0.1	19	17	22	21	64	52	7.8	7.3
15	I50296	Vijayalakshmi	26/f	0.7	0.6	0.4	0.3	0.3	0.3	18	16	15	15	45	43	7.7	7.5
16	I24039	L.Vijaya	32/f	0.6	0.5	0.3	0.2	0.3	0.3	19	13	16	11	50	39	7.6	7.3
17	I31958	K.Srimathy	32/f	0.6	0.8	0.3	0.4	0.3	0.4	17	15	24	15	61	68	7.1	7.4
18	I56390	M.Selvi	27/f	0.6	0.9	0.3	0.5	0.3	0.4	14	12	12	20	42	44	7.0	6.8
19	I36211	V.Valliamma	32/f	0.5	0.6	0.2	0.3	0.3	0.3	14	15	13	18	52	65	7.2	7.2
20	I28243	M.Kujila	30/f	0.3	0.2	0.1	0.1	0.2	0.1	13	15	14	13	42	65	6.9	6.7
21	I36215	B.Rose	32/f	0.9	0.9	0.4	0.4	0.5	0.5	19	20	11	25	58	78	7.0	7.0
22	I58375	P.Amara	24/f	0.3	0.2	0.2	0.1	0.1	0.1	26	23	27	22	41	43	7.0	7.0
23	I36214	S.Vasantha	45/f	0.2	0.2	0.1	0.1	0.1	0.1	18	18	07	18	36	39	7.4	7.2
24	I50527	V.Amuthini	27/f	0.7	0.4	0.3	0.2	0.4	0.2	20	17	09	14	59	60	7.5	7.2
25	I55449	Rathanavathy	31/f	0.3	0.4	0.1	0.2	0.2	0.2	14	15	12	12	52	51	6.7	6.8
26	I54714	J.Anitha	29/f	0.2	0.2	0.1	0.1	0.1	0.1	10	10	11	14	84	85	6.6	6.4
27	I43262	Rajeswari	31/f	0.3	0.3	0.1	0.1	0.2	0.2	14	20	10	30	75	55	6.6	6.5
28	I60109	M.Vimala	30/f	1.0	1.2	0.4	0.5	0.6	0.6	13	15	12	28	49	69	8.0	7.4
29	I53755	G.Ammatchi	36/f	0.3	0.2	0.1	0.1	0.2	0.1	13	12	17	18	69	83	7.3	7.2

30	F82273	V.Jayasree	33/f	1.1	1.0	0.4	0.4	0.7	0.6	17	28	15	24	75	79	7.8	7.2
31	H66126	Shanthi	31/f	0.3	0.2	0.1	0.1	0.2	0.1	16	18	20	25	80	86	7.2	7.4
32	I48333	Bridjetmary	45/f	0.2	0.2	0.1	0.1	0.1	0.1	16	19	16	20	78	79	7.7	7.6
33	I47675	Suganthi	27/f	0.3	0.2	0.1	0.1	0.2	0.1	17	17	17	21	49	55	7.4	6.9
34	G39746	Gomathi	37/f	0.3	0.3	0.1	0.1	0.2	0.2	21	13	14	10	42	50	7.0	7.0
35	I00923	Yuvarani	35/f	0.5	0.3	0.2	0.1	0.3	0.2	17	17	17	15	60	63	7.5	7.1
36	I66325	Manju	27/f	0.4	0.3	0.2	0.1	0.2	0.2	13	17	10	08	61	70	7.0	7.1
37	H96938	Maheswari	27/f	0.8	0.5	0.3	0.2	0.5	0.3	15	22	12	23	52	59	7.9	7.5
38	I68998	K.Prasanna	32/f	0.4	0.3	0.2	0.2	0.2	0.1	11	15	10	08	53	62	7.0	6.5
39	I50605	G.Kala	26/f	0.6	0.6	0.3	0.3	0.3	0.3	18	20	26	14	36	45	7.3	7.1
40	I63726	Manimegalai	22/f	0.4	0.5	0.2	0.2	0.2	0.3	11	18	18	20	43	78	7.7	7.2

S. NO	OP NO	NAME	A/S	Total RBC (milli/cumm)		Renal function test (mg/dl)						WET test for Trichomonas vaginalis	
						Blood urea mg/dl		Sr. creatinie mg/dl		Sr. uric Acid mg/dl			
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I28105	B.Anjali	38/f	4.0	4.2	20	23	0.7	0.8	0.9	2.3	+	-
2	I04794	A.Ramadevi	38/f	4.4	4.4	38	15	0.7	0.9	2.4	2.6	+	-
3	G70637	S.Sasikala	29/f	5.2	4.8	13	14	0.7	0.7	3.5	3.1	+	-
4	I38185	S.Saritha	30/f	4.6	4.6	19	18	0.9	0.9	3.5	4.3	+	-
5	I44538	P.Anjala	31/f	4.0	4.1	17	18	0.8	0.7	2.5	2.8	+	-
6	I41415	A.Suseela	30/f	3.9	4.1	17	16	0.8	0.7	2.1	2.2	+	-
7	I1860	M.Jayasree	35/f	3.9	4.6	12	15	0.7	0.8	4.1	4.1	+	-
8	I31972	V.Shema	30/f	4.6	4.8	18	19	0.7	0.7	4.0	4.0	+	+
9	I34742	S.Radhika	30/f	4.7	4.6	13	14	0.8	0.8	3.5	4.2	+	+
10	I37025	B.Jeyalakshmi	34/f	4.0	4.1	21	22	0.9	0.9	4.9	4.3	+	-
11	I46385	S.Sridevi	21/f	4.1	4.4	0.3	0.4	0.1	0.2	0.2	0.2	+	-
12	I41931	S.Lakshmi	37/f	4.9	4.5	16	15	0.9	0.8	4.1	3.2	+	+
13	I29619	N.Mythili	30/f	4.6	4.8	17	17	1.0	0.9	3.7	3.9	+	+
14	I35655	J.Vijayasree	30/f	4.7	4.6	13	11	0.9	0.8	4.4	4.7	+	-
15	I50296	S.Vijayalakshmi	26/f	4.5	4.5	17	09	0.9	0.8	3.6	2.2	+	-
16	I24039	L.Vijaya	32/f	4.4	4.5	12	16	0.9	0.8	2.1	1.9	-	-
17	I31958	K.Srimathy	32/f	4.3	4.3	16	15	0.7	0.7	2.9	3.1	-	-
18	I56390	M.Selvi	27/f	4.5	4.4	24	16	0.9	0.8	2.2	3.2	-	-
19	I36211	V.Valliamma	32/f	4.5	4.6	19	15	0.8	0.7	4.0	4.0	-	-
20	I28243	M.Kujila	30/f	4.2	4.2	12	13	0.7	0.7	2.4	2.4	-	-
21	I36215	B.Rose	32/f	4.5	4.5	28	29	0.7	0.6	2.3	2.3	-	-
22	I58375	P.Amara	24/f	4.1	4.2	21	21	0.8	0.8	3.6	3.6	-	-
23	I36214	S.Vasantha	45/f	3.8	3.6	23	20	0.8	0.8	3.8	3.8	-	-
24	I50527	V.Amuthini	27/f	4.1	4.2	18	18	0.7	0.8	3.0	2.3	-	-
25	I55449	B.Rathanavathy	31/f	4.6	4.1	16	25	0.7	0.8	3.0	5.0	-	-
26	I54714	J.Anitha	29/f	4.6	4.3	17	20	0.8	0.6	3.4	3.2	-	-
27	I43262	S.Rajeswari	31/f	4.1	4.2	16	32	0.8	1.0	4.2	4.4	-	-

28	I60109	M.Vimala	30/f	4.7	4.7	13	13	0.8	0.8	3.1	3.2	-	-
29	I53755	G.Ammatchi	36/f	4.4	4.3	12	18	0.7	0.8	4.7	4.2	-	-
30	F82273	V.Jayasree	33/f	5.0	5.0	16	17	0.9	0.4	8.2	7.2	-	-
31	H66126	S.Shanthi	31/f	4.3	4.2	17	17	0.7	0.8	4.6	4.3	-	-
32	I48333	S.Bridjetmary	45/f	4.1	4.0	18	17	0.8	0.9	4.6	5.0	+	+
33	I47675	N.Suganthi	27/f	4.6	4.5	15	12	0.7	0.8	2.7	3.1	-	-
34	G39746	H.Gomathi	37/f	4.4	4.2	12	15	0.7	0.8	3.4	2.1	-	-
35	I00923	G.Yuvarani	35/f	4.9	4.6	21	17	0.8	0.8	4.1	2.8	-	-
36	I66325	L.Manju	27/f	4.2	4.1	19	18	0.7	0.7	3.1	3.3	-	-
37	H96938	J.Maheswari	27/f	4.7	4.3	09	14	0.7	0.9	4.2	4.2	-	-
38	I68998	K.Prasanna	32/f	4.6	4.6	12	08	0.8	0.8	2.0	2.0	-	-
39	I50605	G.Kala	26/f	4.5	4.5	22	27	0.8	0.8	4.8	4.3	-	-
40	I63726	Manimegalai	22/f	4.5	4.5	31	30	0.7	0.6	2.9	2.1	-	-

S. NO	**OP NO**	**NAME**	**A/S**	**Lipid profile (mg/dl)**									
				Total cholesterol		**HDL**		**LDL**		**VLDL**		**Triglycerides (Mg/dl)**	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I28105	B.Anjali	38/f	146	117	59	46	76	65	15	10	77	51
2	I04794	A.Ramadevi	38/f	156	108	49	58	85	98	22	16	110	81
3	G70637	S.Sasikala	29/f	175	137	45	46	100	74	28	35	209	173
4	I38185	S.Saritha	30/f	136	131	64	44	76	69	10	13	49	65
5	I44538	P.Anjala	31/f	121	122	63	54	67	65	08	14	38	73
6	I41415	A.Suseela	30/f	137	139	58	44	76	74	18	13	89	66
7	I1860	M.Jayasree	35/f	135	173	60	74	77	91	13	14	63	70
8	I31972	V.Shema	30/f	79	91	41	43	39	41	18	11	88	54
9	I34742	S.Radhika	30/f	122	148	51	53	78	81	23	24	114	122
10	I37025	B.Jeyalakshmi	34/f	124	123	44	46	77	74	16	16	81	81
11	I46385	S.Sridevi	21/f	143	127	68	59	78	70	11	12	56	63
12	I41931	S.Lakshmi	37/f	161	149	49	45	102	84	17	20	86	101

13	I29619	N.Mythili	30/f	159	190	54	53	101	112	22	22	110	110
14	I35655	J.Vijayasree	30/f	130	136	60	55	75	76	17	21	86	105
15	I50296	S.Vijayalakshmi	26/f	120	140	53	59	63	73	12	20	61	101
16	I24039	L.Vijaya	32/f	136	127	35	40	79	73	17	14	84	69
17	I31958	K.Srimathy	32/f	115	123	54	54	73	55	59	12	70	62
18	I56390	M.Selvi	27/f	122	121	51	58	66	63	11	18	52	92
19	I36211	V.Valliamma	32/f	148	147	44	46	85	85	22	24	111	122
20	I28243	M.Kujila	30/f	147	128	45	65	82	69	13	09	64	48
21	I36215	B.Rose	32/f	132	128	53	55	70	70	10	10	50	58
22	I58375	P.Amara	24/f	140	119	48	51	77	67	14	12	70	60
23	I36214	S.Vasantha	45/f	104	94	34	40	56	51	19	15	95	76
24	I50527	V.Amuthini	27/f	148	157	62	68	82	83	13	17	63	87
25	I55449	B.Rathanavathy	31/f	181	174	61	66	107	102	21	12	102	63
26	I54714	J.Anitha	29/f	127	132	32	38	77	78	17	12	87	85
27	I43262	S.Rajeswari	31/f	178	153	50	44	104	98	31	35	152	175
28	I60109	M.Vimala	30/f	207	208	69	69	106	102	13	14	64	70
29	I53755	G.Ammatchi	36/f	208	204	65	66	126	128	17	11	85	76
30	F82273	V.Jayasree	33/f	171	178	59	60	97	98	20	28	100	120
31	H66126	S.Shanthi	31/f	137	142	50	56	76	72	23	28	114	128
32	I48333	S.Bridjetmary	45/f	163	161	56	57	95	90	25	24	129	118
33	I47675	N.Suganthi	27/f	148	143	49	54	75	77	10	12	52	62
34	G39746	H.Gomathi	37/f	151	136	46	46	86	78	13	12	63	62
35	I00923	G.Yuvarani	35/f	151	136	56	53	85	75	11	21	57	104
36	I66325	L.Manju	27/f	127	136	47	46	69	73	11	18	53	93
37	H96938	J.Maheswari	27/f	159	146	45	43	84	77	13	18	63	93
38	I68998	K.Prasanna	32/f	176	158	60	47	102	88	21	22	103	111
39	I50605	G.Kala	26/f	124	128	54	48	68	63	14	14	68	71
40	I63726	Manimegalai	22/f	134	156	66	63	70	80	10	18	51	62

URINE ANALYSIS

S. NO	OP NO	NAME	A/S	URINE ANALYSIS							
				Albumin		Sugar		Deposits			
								Pus cells		Epi cells	
				BT	AT	BT	AT	BT	AT	BT	AT
1	I28105	B.Anjali	38/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	2-4
2	I04794	A.Ramadevi	38/f	NIL	NIL	NIL	NIL	1-2	6-8	1-2	4-6
3	G70637	S.Sasikala	29/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2
4	I38185	S.Saritha	30/f	NIL	NIL	NIL	NIL	3-5	2-4	PLENTY	2-4
5	I44538	P.Anjala	31/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	1-2
6	I41415	A.Suseela	30/f	NIL	NIL	NIL	NIL	3-5	2-3	2-4	4-5
7	I1860	M.Jayasree	35/f	NIL	NIL	NIL	NIL	3-5	1-2	4-6	1-2
8	I31972	V.Shema	30/f	NIL	NIL	NIL	NIL	1-2	2-3	1-2	1-2
9	I34742	S.Radhika	30/f	NIL	NIL	NIL	NIL	1-2	4-5	1-3	2-3
10	I37025	B.Jeyalakshmi	34/f	NIL	NIL	NIL	NIL	4-6	4-5	3-5	1-2
11	I46385	S.Sridevi	21/f	NIL	NIL	NIL	NIL	2-4	1-2	2-4	1-2
12	I41931	S.Lakshmi	37/f	NIL	NIL	NIL	NIL	2-4	2-4	24	2-3
13	I29619	N.Mythili	30/f	NIL	NIL	NIL	NIL	4-6	2-4	4-6	2-4
14	I35655	J.Vijayasree	30/f	NIL	NIL	NIL	NIL	2-4	2-4	2-4	2-4
15	I50296	S.Vijayalakshmi	26/f	NIL	NIL	NIL	NIL	2-3	2-4	2-3	2-4
16	I24039	L.Vijaya	32/f	NIL	NIL	NIL	NIL	2-4	2-4	1-2	1-2
17	I31958	K.Srimathy	32/f	NIL	NIL	NIL	NIL	2-3	2-3	2-3	1-2
18	I56390	M.Selvi	27/f	NIL	NIL	NIL	NIL	3-5	2-4	3-5	1-2
19	I36211	V.Valliamma	32/f	NIL	NIL	NIL	NIL	6-7	1-2	2-4	1-2
20	I28243	M.Kujila	30/f	NIL	NIL	NIL	NIL	4-6	1-2	4-7	1-2
21	I36215	B.Rose	32/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	3-4
22	I58375	P.Amara	24/f	NIL	NIL	NIL	NIL	2-4	4-6	2-4	2-4
23	I36214	S.Vasantha	45/f	NIL	NIL	NIL	NIL	2-3	1-2	2-3	1-2
24	I50527	V.Amuthini	27/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	1-4
25	I55449	B.Rathanavathy	31/f	NIL	NIL	NIL	NIL	10-12	4-6	6-7	3-5
26	I54714	J.Anitha	29/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	2-4
27	I43262	S.Rajeswari	31/f	NIL	NIL	NIL	NIL	2-3	2-4	2-3	2-4

28	I60109	M.Vimala	30/f	NIL	NIL	NIL	NIL	2-3	1-2	2-3	1-2
29	I53755	G.Ammatchi	36/f	NIL	NIL	NIL	NIL	2-4	1-2	1-2	1-2
30	F82273	V.Jayasree	33/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2
31	H66126	S.Shanthi	31/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	2-4
32	I48333	S.Bridjetmary	45/f	NIL	NIL	NIL	NIL	PLENTY	1-2	6-7	2-4
33	I47675	N.Suganthi	27/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	1-2
34	G39746	H.Gomathi	37/f	NIL	NIL	NIL	NIL	1-2	4-5	1-2	1-2
35	I00923	G.Yuvarani	35/f	NIL	NIL	NIL	NIL	PLENTY	4-5	2-4	1-2
36	I66325	L.Manju	27/f	NIL	NIL	NIL	NIL	4-5	1-2	2-3	4-5
37	H96938	J.Maheswari	27/f	NIL	NIL	NIL	NIL	1-2	1-2	2-3	2-3
38	I68998	K.Prasanna	32/f	NIL	NIL	NIL	NIL	1-2	1-2	2-4	1-2
39	I50605	G.Kala	26/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	1-2
40	I63726	Manimegalai	22/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	2-4

ANALYSIS OF TRIAL DRUG

CHEMICAL ANALYSIS

Preparation of extract:

25 ml of Mega rajanga kirutham is measured accurately and placed in a 250 ml of clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of the sample	Straw color	
I.	Test For Acid Radicles		
1.	**Test for Sulphate:** 2 ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution.	No cloudy appearance.	Absence of Sulphate.
2.	**Test for Chloride:** 2 ml of the above prepared extract is added with dil. Hno_3 till the effervescence ceases. Then 2 ml of silver nitrate solution is added.	Cloudy appearance present.	**Presence of Chloride.**
3.	**Test for Phosphate:** 2ml of the extract is treated with 2ml of ammonium molybdate solution and 2ml of con.Hno_3.	No cloudy yellow appearance.	Absence of Phosphate.
4.	**Test for Carbonate**: 2ml of the extract is treated with 2ml magnesium sulphate solution.	Cloudy appearance present.	**Presence of Carbonate.**
5.	**Test for Nitrate:** 1 drop of the substance is heated with copper turnics and concentrated H_2SO_4 and viewed the test tube vertically down.	No characteristic changes.	Absence of nitrate.
6.	**Test for Sulphide:** 1 ml of the substance is treated with 2 ml of con.HCL.	No rotten egg smelling gas evolved.	Absence of Sulphide.
7.	**Test for Fluride & Oxalate:** 2 ml of the extract is added with 2ml of dil. Acetic acid and 2 ml calcium chloride solution and heated.	No cloudy appearance.	Absence of Fluride and Oxalate.
8.	**Test for Nitrite:** 3 drops of the extract is placed on filter paper on that 2 drops of acetic acid and 2 drops Benzidine solution is placed.	No characteristic changes.	Absence of Nitrite.

9.	**Test for Borate:** 2 pinches of the substance is made into paste by using sulphuric acid and alcohol (95%) and introducer into the blue flame.	Bluish green color flame not appeared.	Absence of Borate.
II.	**Test for Basic Radicles**		
1.	**Test for Lead:** 2 ml of the extract is added with 2 ml of Potassium iodide solution.	No yellow precipitate is obtained.	Absence of Lead.
2.	**Test for Copper:** One pinch of substance is made into paste with con.HCL in a watch glass and introduced into the non-luminous part of the flame.	No blue color flame.	Absence of copper.
3.	**Test for Aluminum:** To the 2ml of the extract sodium hydroxide is added in drops to excess.	No characteristic changes.	Absence of Aluminium.
4.	**Test for Iron:** a. To the 2 ml of extract add 2 ml of ammonium thiocynate solution. b. To the 2ml of extract 2 ml ammonium thiocynate solution and 2 ml of con.HNO_3 is added.	Mild red color appeared. Blood red color appeared.	**Presence of Iron.** **Presence of Iron**.
5.	**Test for Zinc:** To 2ml of the extract sodium hydroxide solution is added in drops to excess.	White precipitate is not appeared.	**Presence of Zinc.**
6.	**Test for Calcium:** 2 ml of the extract is added with 2ml of 4% ammonium oxalate solution.	No Cloudy appearance.	Absence of Calcium.
7.	**Test for Magnesium:** To 2ml of extract sodium hydroxide solution is added in drops to excess.	White precipitate is obtained.	**Presence of Magnesium.**
8.	**Test for Ammonium**: To 2 ml of extract few ml of Nessler's reagent and excess of sodium hydroxide solution are added.	No brown color appeared.	Absence of ammonium.
9.	**Test for Potassium:** 1 ml of substance is treated with 2ml of sodium nitrate solution and then treated with 2ml of cobalt nitrate in 30% glacial acetic acid.	No yellowish precipitate is obtained.	Absence of Potassium.

10.	**Test for Sodium:** 2 pinches of the substance is made into paste by using HCL and introduced into the blue flame of Bunsen burner.	No yellow color flame appeared.	Absence of sodium.
11.	**Test for Mercury:** 2 ml of the extract is treated with 2 ml of sodium hydroxide solution.	No yellow precipitate is appeared.	Absence of mercury.
12.	**Test for Arsenic:** 2 ml of the extract is treated with 2 ml of sodium hydroxide solution.	No brownish red precipitate is obtained.	Absence of Arsenic.
III.	**Miscellanious**		
1.	**Test for Starch:** 2ml of the extract is treated with weak iodine solution.	No blue color developed.	Absence of starch.
2.	**Test for Reducing sugar:** 5 ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for two minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The color changes are noted.	No brick red color developed.	Absence of Reducing sugar.
3.	**Test for the Alkaloids:** 2 ml of extract is treated with 2 ml of picric acid.	Yellow color developed.	**Presence of Alkaloid.**
4.	**Test for Tannic acid:** 2 ml of extract is treated with 2 ml of ferric chloride solution.	Black color precipitate is obtained.	**Presence of Tannic acid.**
5.	**Test for Unsaturated compound:** To the 2 ml of extract 2 ml of Potassium permanganate solution is added.	Potassium permanganate is not decolorized.	Absence of Unsaturated compound.
6.	**Test for Amino acid:** 2 drops of the extract is placed on a filter paper and dried well.	No violet color developed.	Absence of amino acid.
7.	**Test for Type of Compound:** 2 ml of the extract is treated 2 ml of ferric chloride solution.	No green color developed. No red color developed. No violet color	Absence of oxyquinole epinephrine and pyro catechol. Anti pyrine, Aliphatic amino acids and meconic acid are absent. Apomorphine

		developed. No blue color developed.	salicylate and Resorcinol are absent. Morphine, Phenol cresol and hydro quinine are absent.

Result:

The chemical study of the trial drug reveals **Calcium, Carbonate, Iron, Zinc, Magnesium, Alkaloid and Tannic acid.**

Physicochemical evaluation of Mega rajanga kirutham

Project ID : NRS/AS/0024/02/2017

Institute : National Institute of siddha,Chennai

Sample Name : Mega rajangakritham

Sample ID : MRK

Percentage Loss on Drying

10gm of test drug (weight equivalent to oil) was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug (weight equivalent to oil) was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of pH

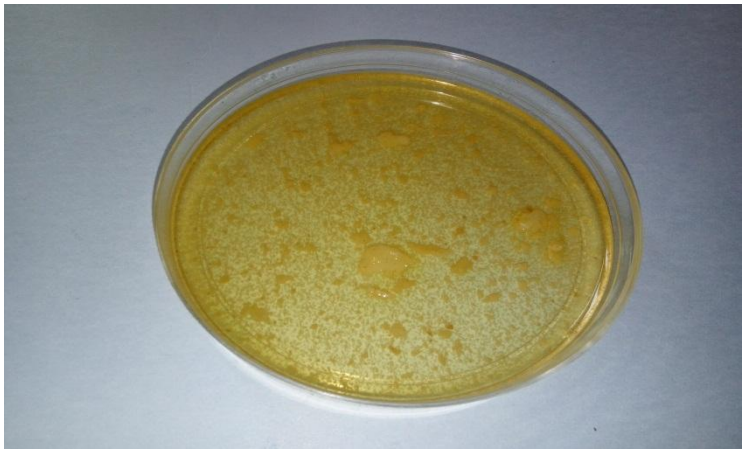
Sample being oily in nature the direct litmus evaluation method was adopted to check the pH of the sample.

Determination of Iodine value

About 20 gm of oil was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about 25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for anhour.T About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2 gm(weight equivalent to oil) of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeatthe same procedure with out taking the sample for blank titration . Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.



Final Test report

Parameter	**Observation**
Color	Yellowish
Smell	Characteristic
Touch	Greasy
Appearance	Turbid

S.No	**Parameter**	**Mean (n=3) SD**
1	***Loss on Drying at 105 °C (%)***	8.03 ± 1.09
2	***Total Ash (%)***	0.788 ± 0.37

S.No	Specific Test	MRK
1	***pH***	6
2	***Refractive index***	1.48
3	***Iodoine value (mg I2/g)***	101
4	***Saponification Value (mg of KOH to saponify 1gm of fat)***	205

Reference:

1. India Pharmacopeia I Volume I, Government of India, Ministry of Health and Family welfare, Indian Pharmacopeia commission, 2014.
2. Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of Indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH .Ministry of Health & Family Welfare, Govt. of India
3. Indian standard methods of sampling and test for oils and fats Indian standard institution New Delhi 47-50. 1964

Phyto chemical analysis of Mega rajanga kirutham

Sample Preparation

Mega rajanga kirutham (MRK) was extracted with hexane and the extract was subjected to the following analysis

Test for Alkaloid- Mayer's reagent

To the test drug about 2ml of Mayer's reagent was added and was observed for the presence of alkaloids. Appearance of dull white precipitate indicates the presence of alkaloids.

Test for flavonoid

To 0.1ml of the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for Glycosides -Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for Triterepnoids

To the test solution 2ml chloroform was added with few drops of conc. Sulphuric acid (3ml) at the side of the test tube. An interface with a reddish brown coloration is formed if terpenoids constituent is present.

Test for Steroids - Salkowski test

To the test solution 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Test for Carbohydrates - Benedict's test

To 0.5 ml of test drug about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

Test – Phenol- Lead acetate test

The test sample is dissolved in of distilled water and to this 3 ml of 10% lead acetate solution is added. A bulky white precipitate indicates the presence of phenolic compounds.

Test for tannins

About 0.5ml of test sample is boiled in 20 mL of distilled water in a test tube and then filtered. The filtration method used here is the normal method, which includes a conical flask and filter paper. The 0.1% FeCl3 is added to the filtered samples and observed for brownish green or a blue black coloration, which shows the presence of tannins

Test for Saponins

The test drugs were shaken with water vigorously for 10 mins , copious lather formation indicates the presence of saponins.

Test for Proteins (Biuret Test)

Biuret test: Equal volume of 5% solution of sodium hydroxide and 1% copper sulphate were added. Appearance of pink or purple colour indicates the presence of proteins and free amino acids.

Test of Coumarins

1 ml of extract, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for Anthocyanin

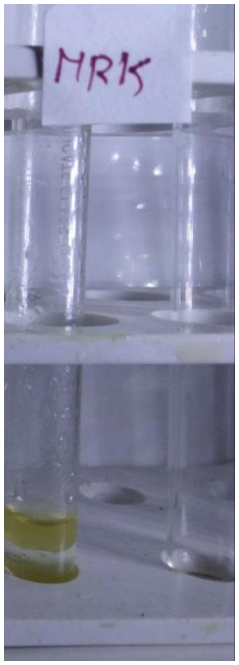
About 0.2 ml of the extract was weighed in separate test tube, 1ml of 2N Sodium hydroxide was added, and heated for 5 minutes at 100 ± 2°C. Observed for the formation of bluish green color which indicates the presence of anthocyanin.

Reference

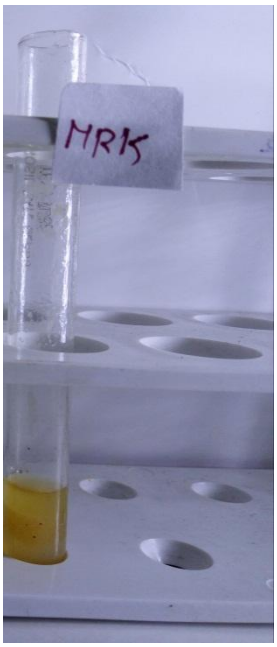
Brain KR, Turner TD. The Practical Evaluation of Phytopharmaceuticals. Bristol:Wright-Scientechnica; 1975:36-45

RESULTS

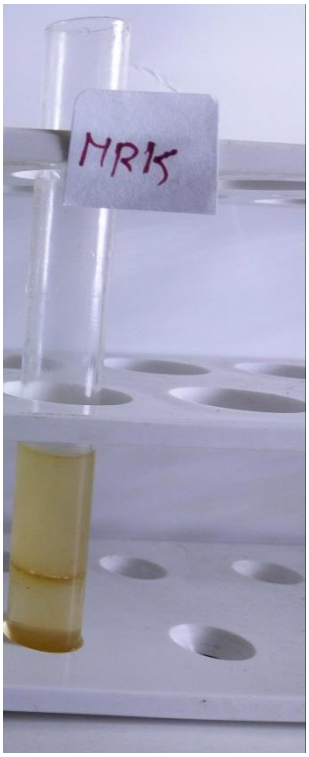
Test for Alkaloid- Mayer's reagent



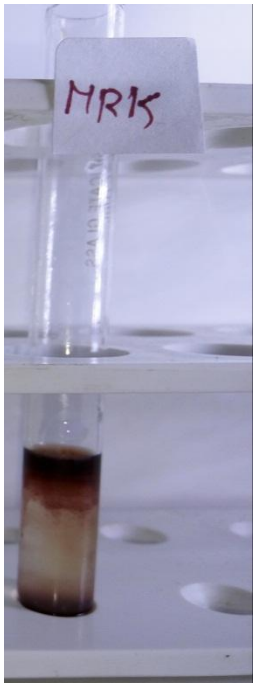
Test for flavonoid



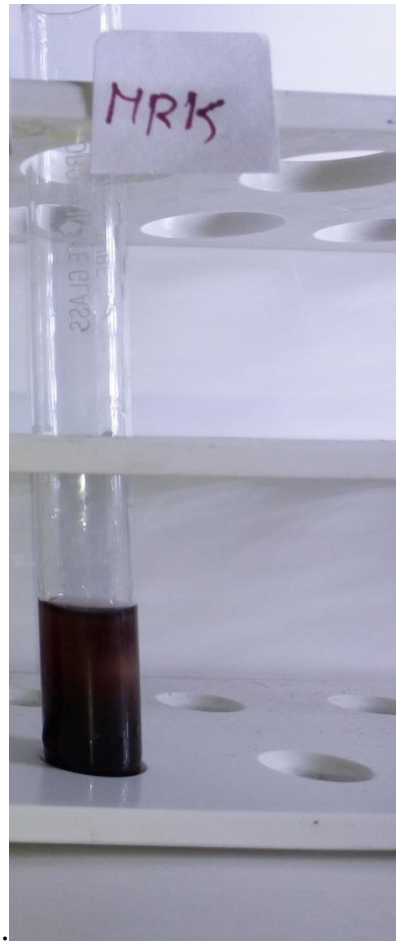
Test for Glycosides -Borntrager's Test



Test for Triterepnoids

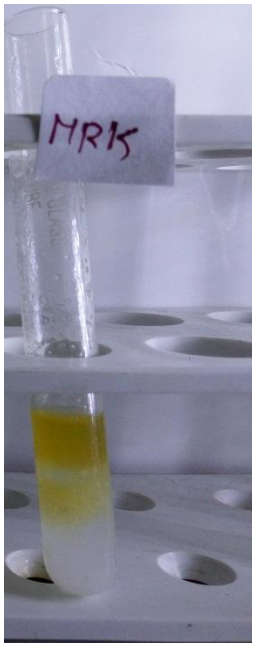


Test for Steroids - Salkowski test

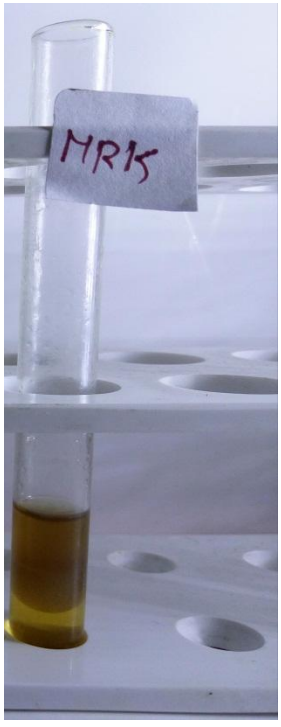


Test for Carbohydrates - Benedict's test

Test – Phenol- Lead acetate test

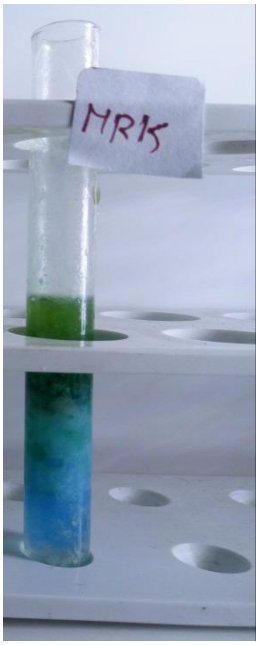


Test for tannins

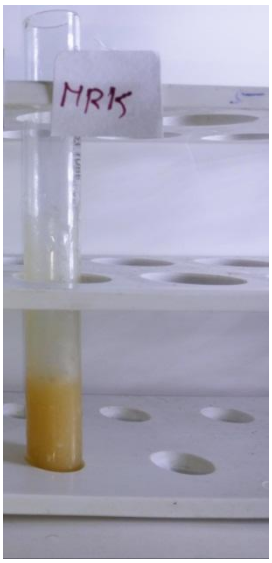


Test for Saponins

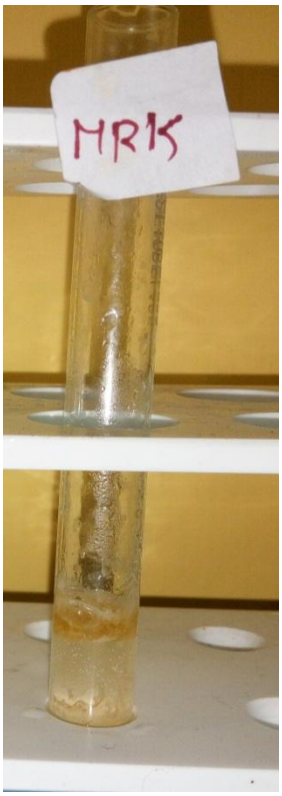
Test for Proteins (Biuret Test)



Test of Coumarins



Test for Anthocyanin



PHYTOCOMPONENTS	MRK
ALKALOIDS	**-**
FLAVONOIDS	**+**
GLYCOSIDES	**-**
STEROIDS	**+**
SUGAR	**+**
TRITEREPNOIDS	**+**
COUMARINS	**+**
PHENOLS	**+**
TANNINS	**-**
SAPONINS	**-**
PROTEINS	**+**
ANTHOCYANIN	**-**

\+ Indicates positive

\- Indicates Negative

Quantitative estimation of phytoconstituents of Mega rajangakritham

Determination of total Phenol content

The total phenol content was determined using Folin–Ciocalteu reagents with analytical grade Gallic acid as the standard. 1 ml of sample was added to deionized water (10 ml) and Folin–Ciocalteu phenol reagents (1ml). After 5 minutes, 20% sodium carbonate (2 ml) was added to the mixture. After being kept in total darkness for 1 hr, the absorbance was measured at 750 nm using a spectrophotometer. Amounts of total Phenol was calculated using Gallic acid calibration curve. The results were expressed as Gallic acid equivalents (GAE) mg/g of dry plant matter.

Reference

Ganesh N. Sh

arma K, Nitin S, Jyotsana S. Phytochemical screening and estimation of Total Phenolic Content in *Aeglemarmelos*Seeds. *Int J PharmaClinc Res*.2011; 3(2): 27-29.

Total Flavonoid

Total flavonoid content in the drug MRK was determined using aluminum chloride method . In this method Quercetin was used as standard and flavonoid contents were measured as quercetinequivalent. For this purpose, the calibration curve of quercetin was drawn. 1ml of standard or sample MRK was taken into 10ml volumetric flask, containing 4ml of distill water. 0.3ml of 5%$NaNO_2$ added to the flask. After 5min, 0.3ml 10%$AlCl_3$ was added to the mixture. At the 6th min add 2ml of 1M NaOH was added and volume made up to 10ml with distills water. The absorbance was noted at 510nm using UV-Visible spectrophotometer.

Reference

Olajire A. A and Azeez L Total antioxidant activity, phenolic, flavonoid and ascorbic acid contents of Nigerian vegetables., 2011; 2(2) 022-029,African Journal of Food Science and Technology

Phyto- constituents	**MRK**
Total phenols (GAE mg/gm)	0.934 ± 0.04
Total flavanoids (Quercetin mg/gm)	2.82 ± 0.42

Mean with 3 replicates ± SD.

Anti inflammatory activity of Mega rajanga kirutham

In-vitro Anti-Inflammatory Activity by Protein (Albumin) denaturation Assay

Project ID : NRS/AS/0025/02/2017

Institute : National Institute of Siddha

Sample Name : Mega rajangakritham

Sample ID : MRK

Sample Stock prepared using Hexane

Albumin Denaturation Assay Procedure

In-vitro anti-inflammatory activity Mega rajangakritham (MRK) was studied using albumin denaturation technique. The reaction mixture consisted of bovine serum albumin (5% aqueous solution) and test sample MRK at varying concentration ranges from 100 to 500 mcg/ml and standard diclofenac sodium at the concentration of100 mcg/ml of final volume. pH was adjusted by using a small amount of 1N Hydrochloric acid. The samples were incubated at 37°C for 20 min and then heated at 57°C for 3 min. After cooling the sample, 2.5 ml of phosphate buffer solution was added into each test tube. Turbidity developed was measured spectrophoto-metrically at 660 nm, for control distilled water was used instead of test sample while product control tests lacked bovine serum albumin. The experiment was performed in triplicate.

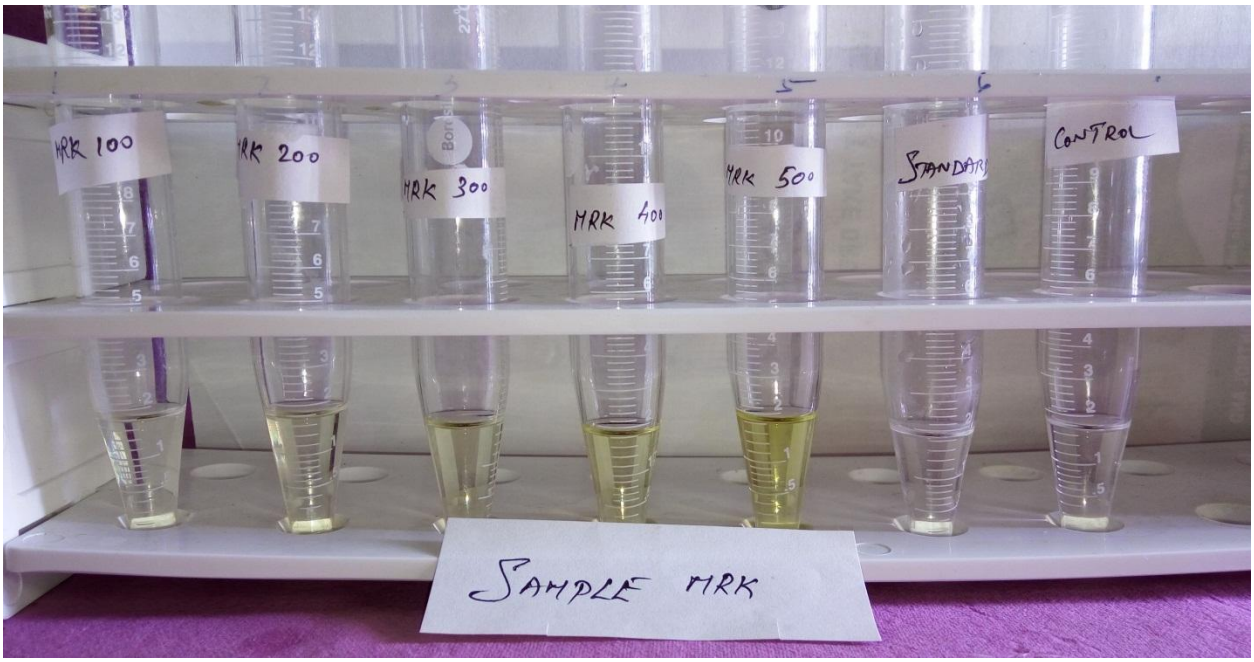
The Percentage protection from denaturation is calculated by using the formulae

$$\left[\frac{(A)_{\text{control}} - (A)_{\text{sample}}}{(A)_{\text{control}}}\right] \times 100.$$

Statistical analysis

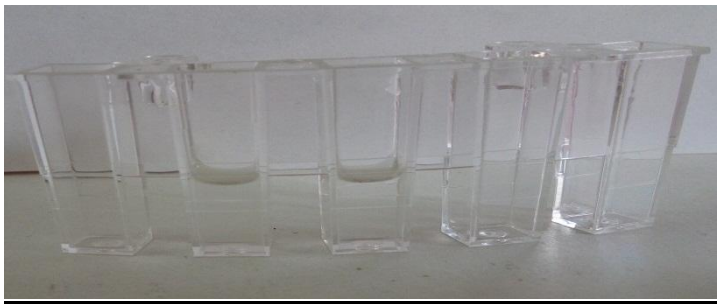
Results are expressed as Mean ± SD. The difference between experimental groups was compared by One-Way Analysis Of Variance (ANOVA) followed by Dunnet Multiple comparison test

Preparation of Test and control

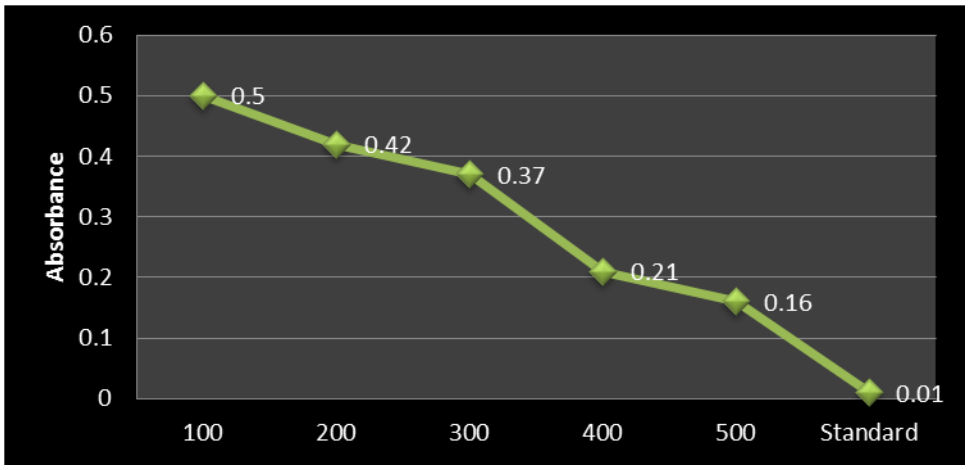


Absorbance of reaction mixture – Test Sample

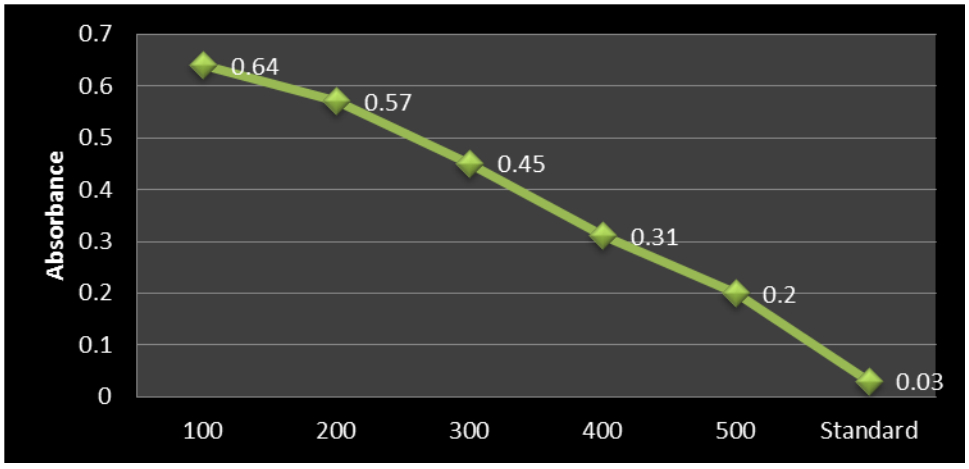
Absorbance of reaction mixture – Control and Standard



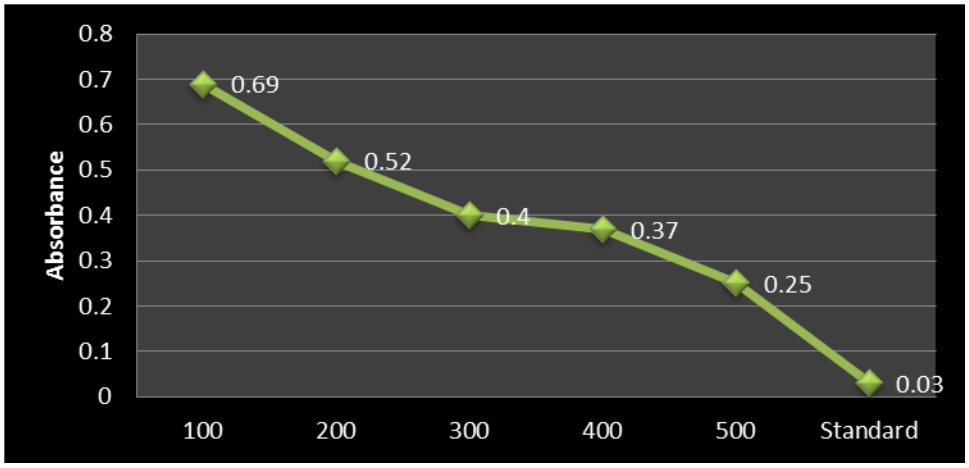
Absorbance Range of test and standard at Trial 1



Absorbance Range of test and standard at Trial 2



Absorbance Range of test and standard at Trial 3



FINAL RESULT

Concentration in µg/ml	Absorbance
Control	0.917 ± 0.020
MRK 100	0.61 ± 0.098
MRK 200	0.503 ± 0.076
MRK 300	0.406 ± 0.040
MRK 400	0.296 ± 0.080
MRK 500	0.203 ± 0.045
Diclofenac sodium (100 µg)	0.023 ± 0.011

Each value represents the mean ± SD. N=3

Concentration in µg/ml	Percentage Inhibition of Protein Denaturation
MRK 100	25.18 ± 13.2
MRK 200	36.89 ± 8.97
MRK 300	47.46 ± 4.49
MRK 400	59.34 ± 10.9

MRK 500	**69.54 ± 7.22**
Diclofenac sodium (100 µg)	**89.22 ± 2.83**

Each value represents the mean ± SD. N=3

Result Analysis

The result obtained from the present clearly indicates that the test drug MRK was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 69.54 % was observed at 500 µg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 89.22 % at the concentration of 100 µg/ml.

Conclusion

From the result of the study it was concluded that the test drug MRK possess promising anti-inflammatory property in protein denaturation assay.

Reference

1. G.Leelaprakash, S.MohanDass. In-vitro anti-inflammatory activity of methanol extract of enicostemmaaxillare. Int. J. Drug Dev. & Res., 2011, 3 (3): 189-196.
2. M. V. Anoop, A. R. Bindu . In-vitro Anti-inflammatory Activity Studies on Syzygiumzeylanicum (L.) DC Leaves. International Journal of Pharma Research & Review, August 2015; 4(8):18-27.

Anti microbial activity of Mega rajanga kirutham

Purpose: Anti- Microbial Profiling

Project Id : NRS/AS/0025/02/2017

Total Sample : 01

Sample ID : MRK

Institute : National Institute of Siddha, Chennai

Disc-diffusion method:

The antibacterial activities of the sample MRK were carried out by disc diffusion method. The concentrations of the test compounds were used at the concentration of 500, 1000, 2000 µg. The target microorganisms were cultured in Mueller–Hinton broth (MHB). After 24 h the suspensions were adjusted to standard sub culture dilution. The Petri dishes containing Muller Hinton Agar (MHA) medium were cultured with diluted bacterial strain.Diamond's mediumused for incubation of*Trichomonasvaginalis*. Disc made of Whatman No.1, diameter 6 mm was pre-sterilized and was maintained in aseptic chamber.Each concentration was injected to the sterile disc papers. Then the prepared discs were placed on the culture medium.Standard drug Ciprofloxacin (5µg) for anti-bacterial /Metronidazole (5µg) for *Trichomonasvaginalis*and Fluconazole (25µg) was used as a positive reference standard to determine the sensitivity of each microbial species tested. Then the inoculated plates were incubated at 37^{o} C for 24 h (Bacterial) - 72 hr (Fungal).The diameter of the clear zone around the disc was measured and expressed in millimeters as its anti-microbial property. The results were depicted in Table.

Organisms used for Anti-Bacterial Activity

s.no	**organisms**
1.	***E-Coli***
2.	***Staphylococcus aureus***
3.	***TrichomonasVaginalis***
4.	***Candida albicans***

5.	***Aspergillusniger***

Zone of Inhibition data of Anti-Microbial activity

Sample Code	***E-Coli***			***Staphylococcus aureus***			***Trichomonas Vaginalis***			***Candida albicans***			***Aspergillusniger***		
Concentration	**500 µg**	**1000 µg**	**2000 µg**	**500 µg**	**1000 µg**	**2000 µg**	**500 µg**	**1000 µg**	**2000 µg**	**500 µg**	**1000 µg**	**2000 µg**	**500 µg**	**1000 µg**	**2000 µg**
MRK	**-**	**2**	**4**	**-**	**4**	**8**	**-**	**3**	**6**	**-**	**-**	**3**	**-**	**-**	**-**
Ciprofloxacin (10µg)	**24**			**19**			**NA**			**NA**			**NA**		
Metronidazole (5µg)	**NA**			**NA**			**22**			**NA**			**NA**		
Fluconazole (25µg)	**NA**			**NA**			**NA**			**20**			**17**		

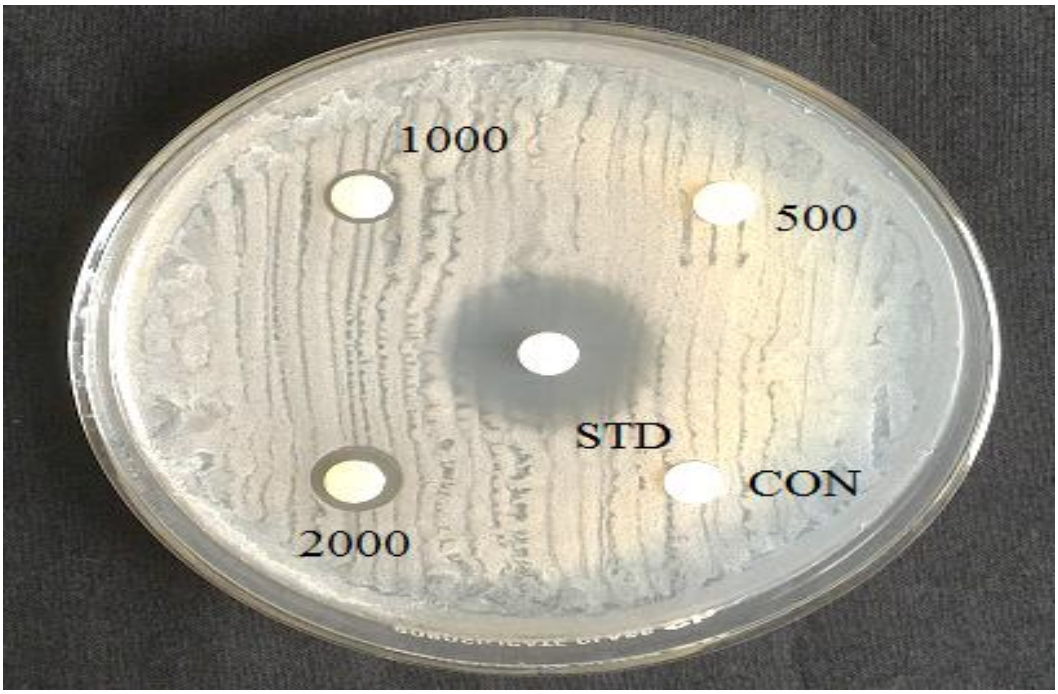
- = Not active
- NA= Not Applicable

Conclusion

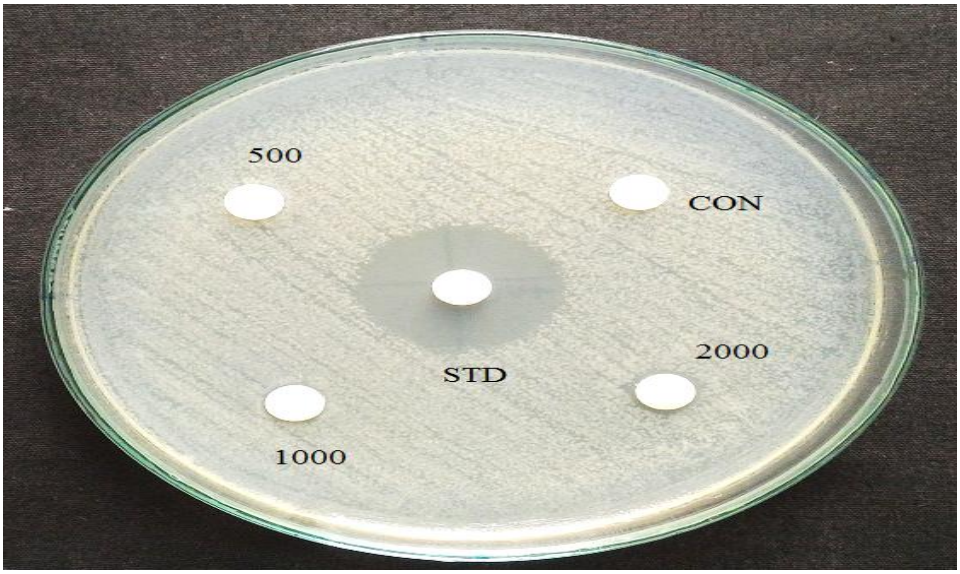
From the results of the present study it was concluded that the sample MRK was effective against *TrichomonasVaginalis,Staphylococcusaureus,E-Coli,Candida albicans and not active againstAspergillusniger*

Anti-Bacterial Evaluation of MRK

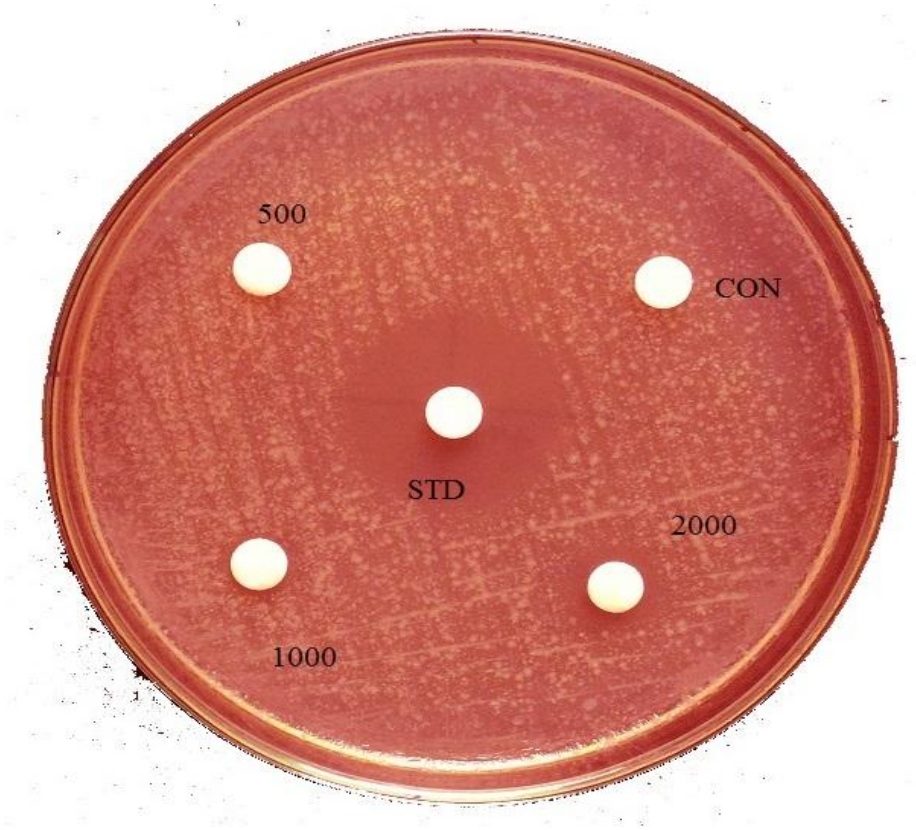
Anti- Microbial Effect of MRK against *Staphylococcus aureus*



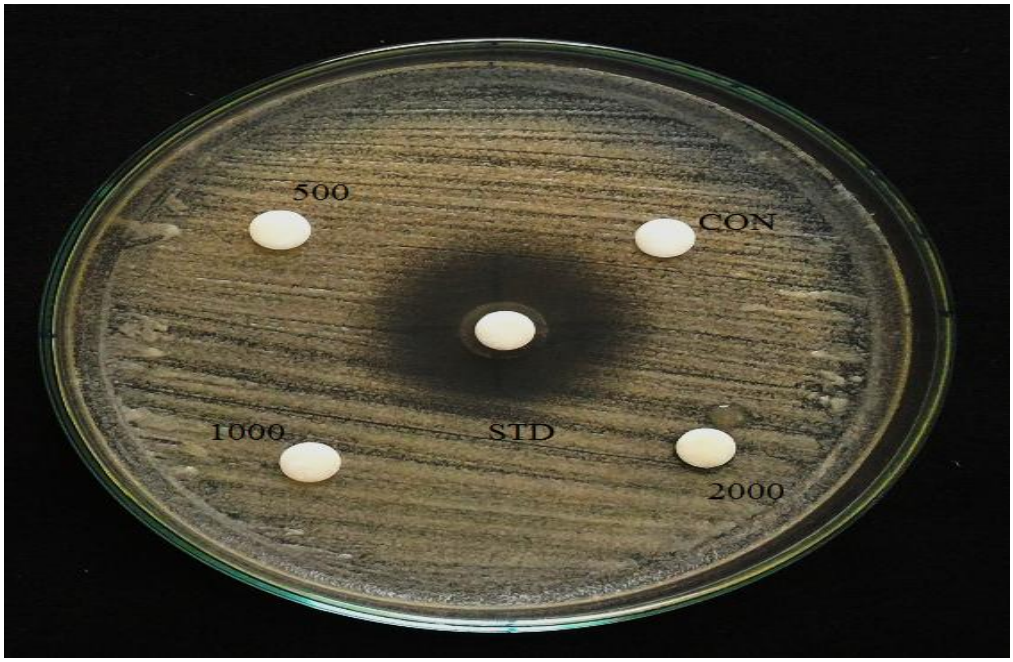
Anti- Microbial Effect of MRK against *E-Coli*



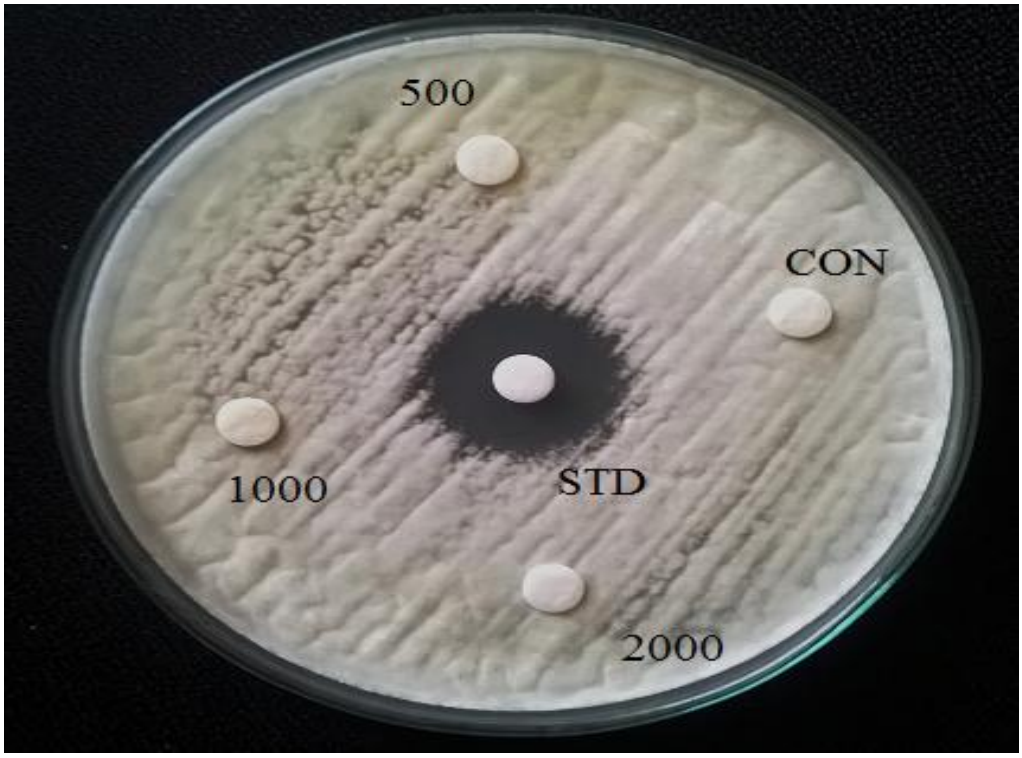
Anti- Microbial Effect of MRK against *TrichomonasVaginalis*



Anti- Microbial Effect of MRK against *Candida albicans*



Anti- Microbial Effect of MRK against *Aspergillusniger*



Anti-Oxidant activity of Mega rajanga kirutham

Project Report

Project Id: NRS/AS/0025/02/2017
Total Sample: 01

Sample :*Mega rajangakritham*

Sample ID: MRK

Institute : National Institute of Siddha, Chennai, Tamil Nadu, India

Purpose: Characterization

DPPH (2, 2-Diphenyl 1-2 picrylhydrazyl) Assay

The antioxidant activity of test drug sample MRK was determined using the 2,2-diphenyl 1-2 picrylhydrazyl (DPPH) free radical scavenging assay . Sample MRK was mixed with 95% methanol to prepare the stock solution in required concentration (10mg/100ml or 100µg/ml). From the stock solution 1ml, 2ml, 4ml, 6ml 8ml and 10ml of this solution were taken in five test tubes and by serial dilution with same solvent were made the final volume of each test tube up to 10 ml whose concentration was then10 µg/ml, 20 µg/ml, 40µg/ml, 60 µg/ml, 80 µg/ml and 100 µg/ml respectively. Ascorbic acid were used as standard was prepared in same concentration as that of the sample extract by using methanol as solvent. Final reaction mixture containing 1 ml of 0.3 mM DPPH methanol solution was added to 2.5 ml of sample solution of different concentrations and allowed to react at room temperature. Absorbance in the presence of test sample MRK at different concentration of (10 µg, 20 µg, 40 µg, 60 µg, 80 µg and 100 µg/ml) was noted after 15 min incubation period at 37^0C. Absorbance was read out at 517 nm using double-beam U.V Spectrophotometer by using methanol as blank.

% scavenging = [Absorbance of control - Absorbance of test sample/Absorbance of control] X 100

The effective concentration of test sample MRK required to scavenge DPPH radical by 50% (IC_{50} value) was obtained by linear regression analysis of dose-response curve plotting between %inhibition and concentrations

Reference

Badami, Omprakash, DongrSH,Suresh B. *In-vitro* Antioxidant property of *SolanumPseudocapsicum* leaf extract. *Indian J Pharmacol*.2005; 37:251-252.

Nitric Oxide Radical Scavenging Assay

The concentrations of test sample MRK are made into serial dilution from 10−100 µg/mL and the standard gallic acid. Griess reagent was prepared by mixing equal amounts of 1% sulphanilamide in 2.5% phosphoric acid and 0.1% naphthylethylenediaminedihydrochloride in 2.5% phosphoric acid immediately before use. A volume of 0.5 mL of 10 mM sodium nitroprusside in phosphate buffered saline was mixed with 1 mL of the different concentrations of the test drug (10−100 µg/mL) and incubated at 25°C for 180 mins. The test drug MRK was mixed with an equal volume of freshly prepared Griess reagent. Control samples without the test drug but with an equal volume of buffer were prepared in a similar manner as was done for the test samples. The absorbance was measured at 546 nm using a Spectra Max Plus UV-Vis microplate reader (Molecular Devices, GA, USA). Gallic acid was used as the positive control. The percentage inhibition of the test drug MRK and standard was calculated and recorded. The percentage nitrite radical scavenging activity of the test drug MRK and gallic acid were calculated using the following formula:

percentage nitrite radical scavenging activity:

$$\text{nitric oxide scavenged } (\%) = \frac{A_{\text{control}} - A_{\text{test}}}{A_{\text{control}}} \times 100,$$

where A_{control} = absorbance of control sample and A_{test} = absorbance in the presence of the samples extracts or standards.

Reference

B. N. Panda, A. B. Raj, N. R. Shrivastava, and A. R. Prathani, "The evaluation of nitric oxide scavenging activity of Acalyphaindica Linn Root," Asian Journal Research Chemistry, vol. 2, no. 2, pp. 148–150, 2009.

ABTS Assay

This assay carried out for the purpose of evaluating the anti-oxidant potential of test drug MRK against 2,2'-azino-bis(3-ethylbenzothiazoline-6-sulphonic acid) or ABTS radicals

The ABTS radical cation method was modified to evaluate the free radical-scavenging effect of one hundred pure chemical compounds. The ABTS reagent was prepared by mixing 5 mL of 7 mM ABTS with 88 µL of 140 mM potassium persulfate. The mixture was then kept in the dark at room temperature for 16 h to allow free radical generation and was then diluted with

water (1 : 44, v/v). To determine the scavenging activity, 100 µL ABTS reagent was mixed with 100 µL of test sample (10-100µg/ml) and was incubated at room temperature for 6 min. After incubation, the absorbance was measured 734 nm. 100% methanol was used as a control.Gallic acid with same concentrations of test drug MRK was measured following the same procedures described above and was used as positive controls. The antioxidant activity of the test sample MRK was calculated using the following equation: The ABTS scavenging effect was measured using the following formula:

$$\text{Radical scavenging (\%)} = \left[\frac{(A)_{\text{control}} - (A)_{\text{sample}}}{(A)_{\text{control}}}\right] \times 100.$$

Reference

N. Pellegrini, M. Ying, and C. Rice-Evans, "Screening of dietary carotenoids and carotenoid-rich fruits extract for antioxidant activities applying 2,2′-azobis (3-ethylbenzothine-6-surfonic acid) radical cationdecolorization assay," Methods in Enzymology, vol. 299, pp. 384–389, 1999.

Results

Percentage inhibition of test drug MRK on DPPH radical scavenging assay

Concentration (µg/ml)	% Inhibition of Ascorbic Acid	% Inhibition of MRK
10 µg/ml	38.15 ± 3.395	7.778 ± 2.222
20 µg/ml	50.37 ± 7.398	16.67 ± 1.925
40 µg/ml	61.11 ± 6.186	23.7 ± 1.697
60 µg/ml	70.74 ± 9.45	29.63 ± 3.395
80 µg/ml	80.37 ± 2.313	35.56 ± 1.925
100 µg/ml	88.15 ± 0.6415	41.85 ± 3.395

Data are given as Mean ± SD (n=3)

IC50 Values for DPPH radical scavenging Assay by MRK and standard.

Test Drug / Standard	IC50 Value DPPH Assay ± SD (µg /ml)
ASCORBIC ACID	**23.55 ± 10.9**
MRK	**121 ± 12.15**

Data are given as Mean ± SD (n=3)

Percentage inhibition of test drug MRK on Nitric Oxide radical scavenging assay

Concentration (µg/ml)	% Inhibition of MRK	% Inhibition of Gallic Acid
10 µg/ml	6.069 ± 2.168	31.07 ± 2.621
20 µg/ml	19.61 ± 3.658	41.14 ± 0.6014
40 µg/ml	26.9 ± 4.21	52.94 ± 1.203
60 µg/ml	32.46 ± 6.831	60.58 ± 1.804
80 µg/ml	43.22 ± 9.679	67.18 ± 7.678
100 µg/ml	55.03 ± 7.536	82.81 ± 0.6014

Data are given as Mean ± SD (n=3)

IC50 Values for Nitric Oxide radical scavenging assay byMRK and standard.

Test Drug / Standard	IC50 Value NO Assay ± SD (µg /ml)
MRK	40.41 ± 2.46
GALLIC ACID	93.74 ± 16.24

Data are given as Mean ± SD (n=3)

Percentage inhibition of test drug MRK on ABTS radical scavenging assay

Concentration (µg/ml)	% Inhibition of MRK	% Inhibition of Gallic Acid
10 µg/ml	13.97 ± 3.772	22.57 ± 3.772
20 µg/ml	20.78 ± 3.281	37.6 ± 4.341
40 µg/ml	27.58 ± 3.873	46.56 ± 5.298
60 µg/ml	36.89 ± 1.24	66.96 ± 2.236
80 µg/ml	44.76 ± 1.86	77.35 ± 3.281
100 µg/ml	55.86 ± 3.772	88.45 ± 1.24

Data are given as Mean ± SD (n=3)

IC50 Values for ABTS radical scavenging assay By MRK and standard.

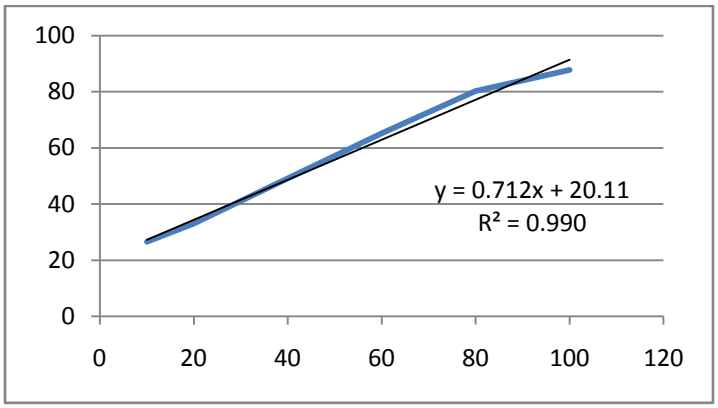
Test Drug / Standard	IC50 Value ABTS Assay ± SD (µg /ml)
MRK	42.48 ± 1.45
GALLIC ACID	89.18 ± 2.81

Data are given as Mean ± SD (n=3)

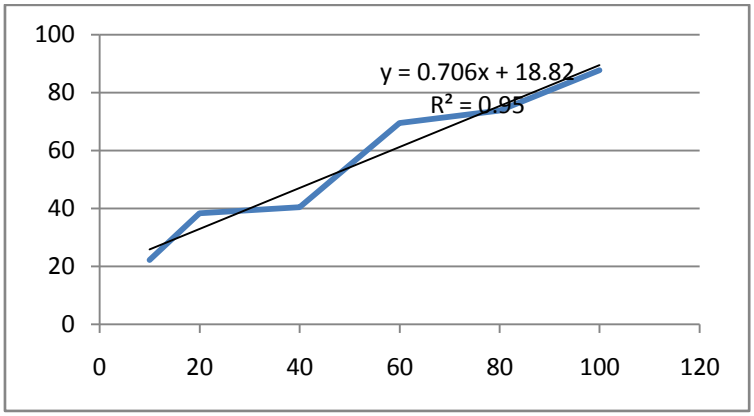
Conclusion

From the results of the present investigation it was concluded that the siddha formulation MRK has promising anti-oxidant activity in the estimated test.

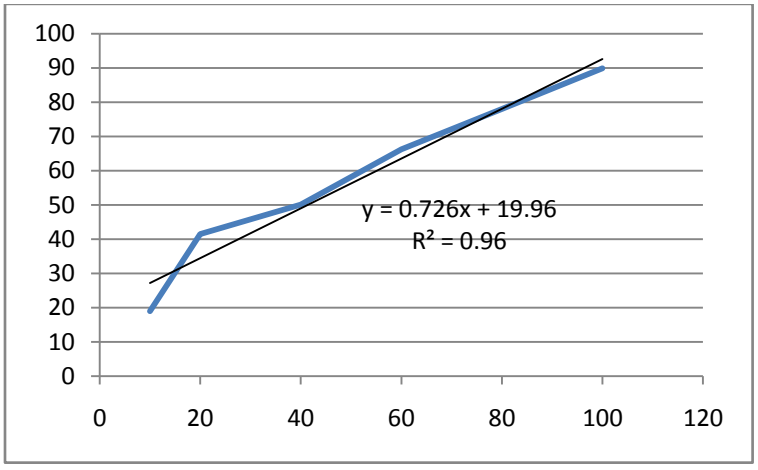
Percentage inhibition ofSTD on ABTS radical scavenging assay



Triplicate 1

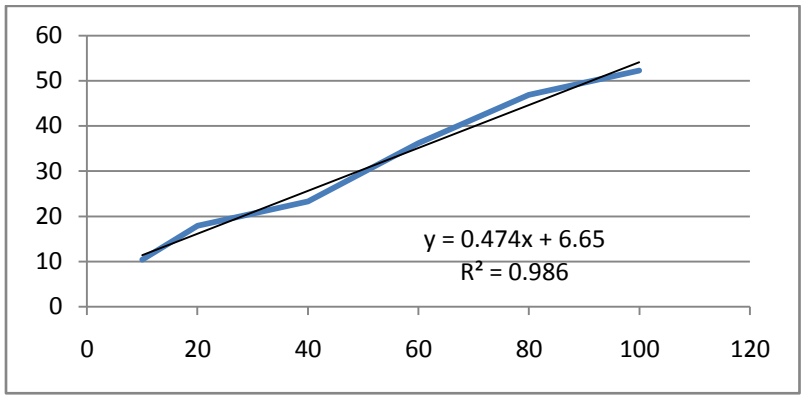


Triplicate 2

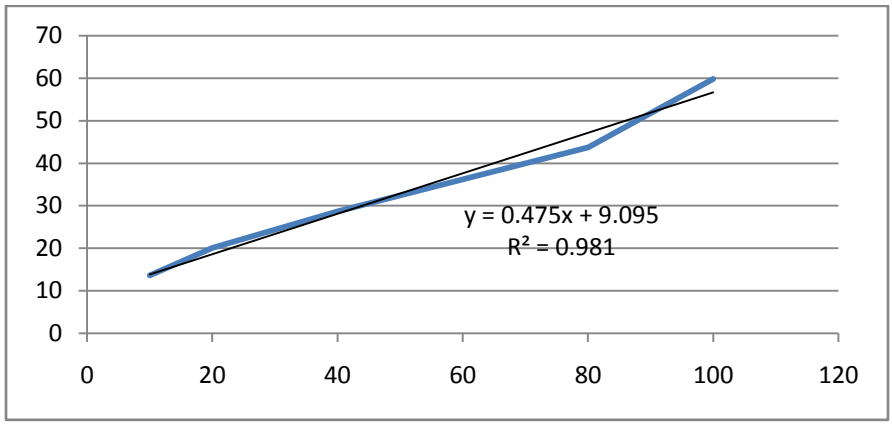


Triplicate 3

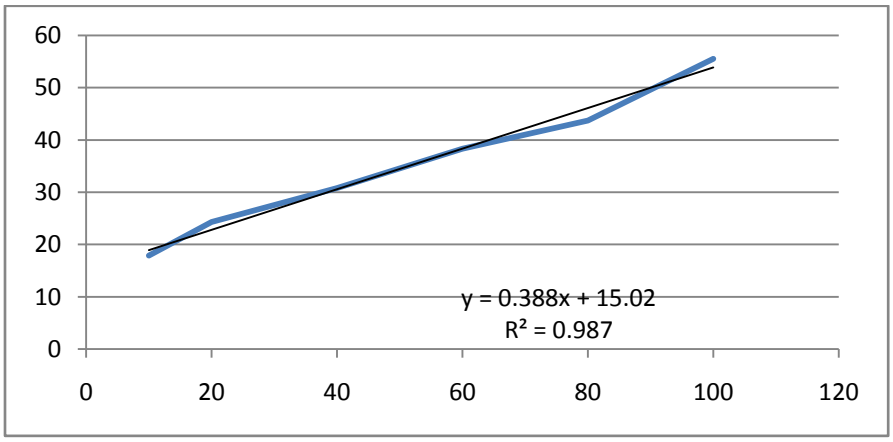
Percentage inhibition ofMRK on ABTS radical scavenging assay



Triplicate 1

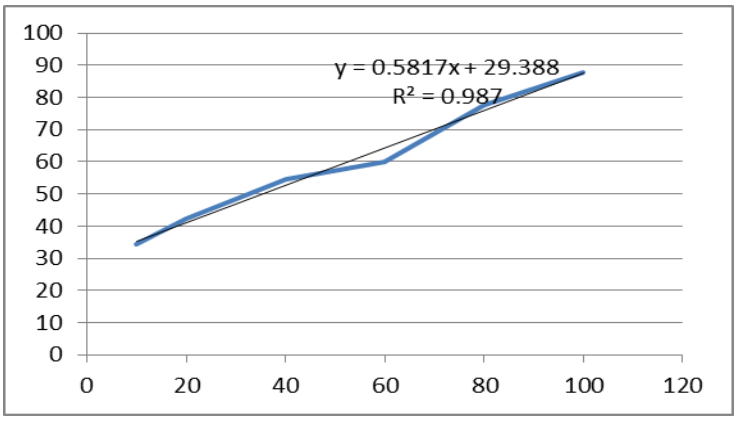


Triplicate 2



Triplicate 3

Percentage inhibition ofSTD on DPPH radical scavenging assay



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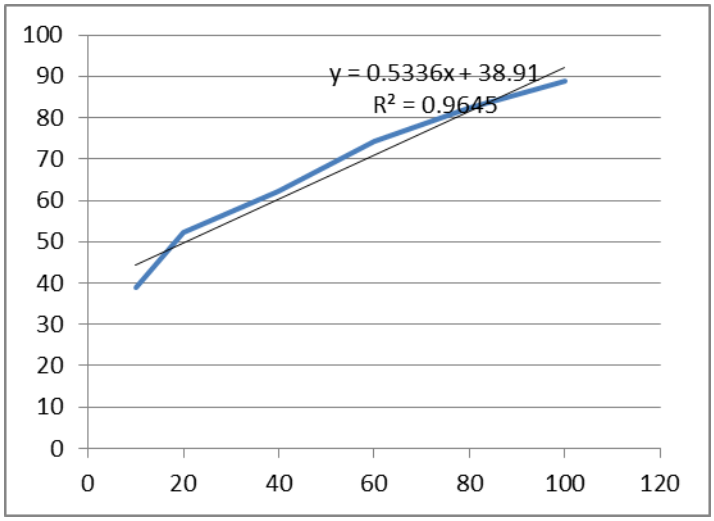

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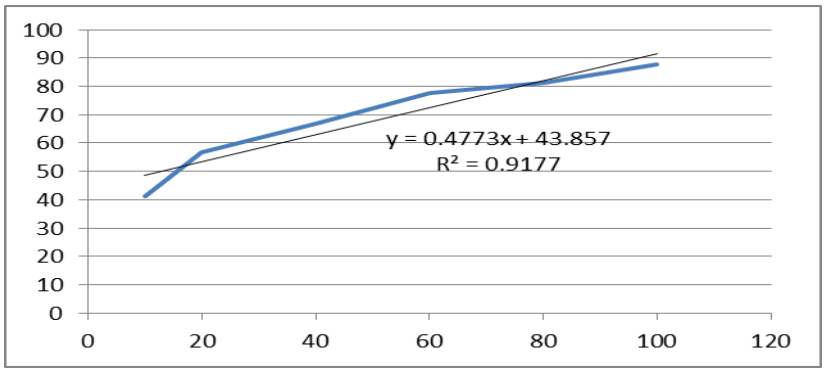
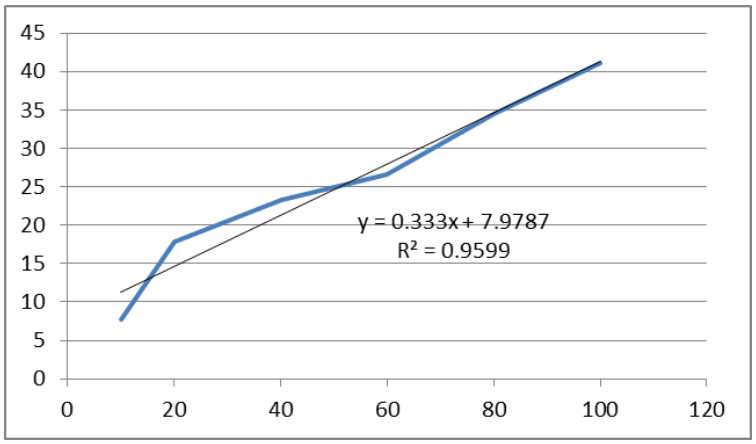


Triplicate 3

Percentage inhibition ofMRK on DPPH radical scavenging assay



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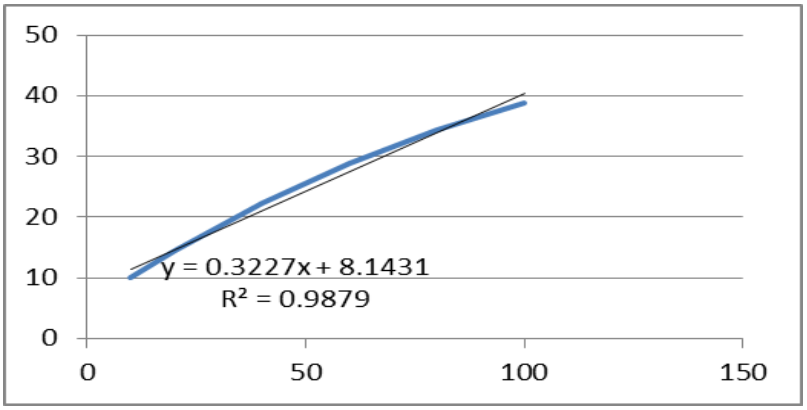

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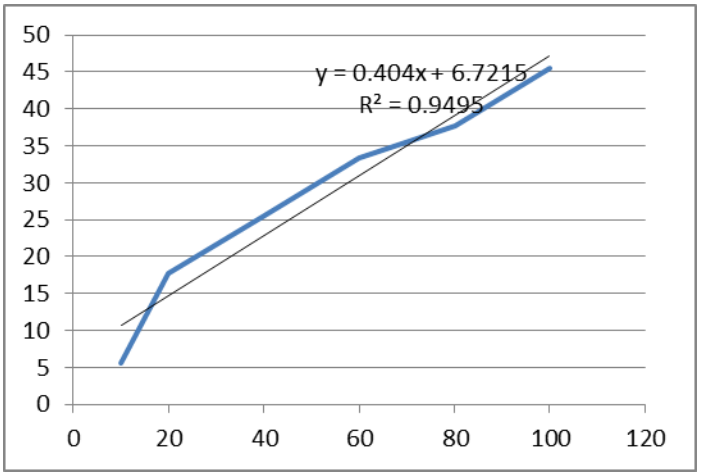
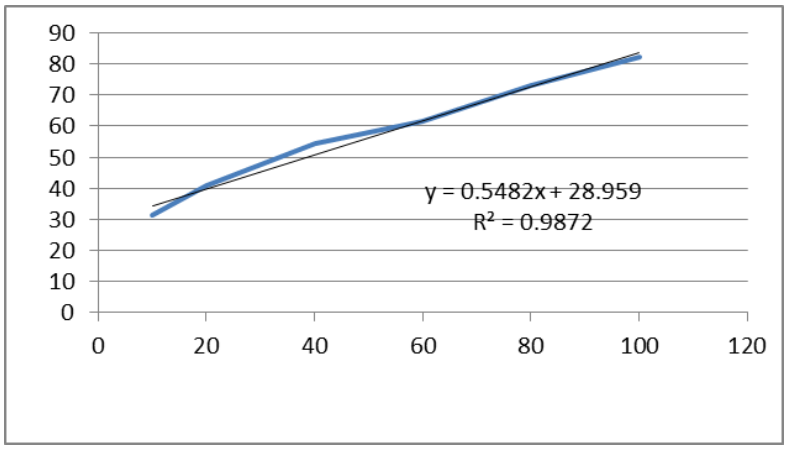


Triplicate 3

Percentage inhibition ofSTD on NO radical scavenging assay



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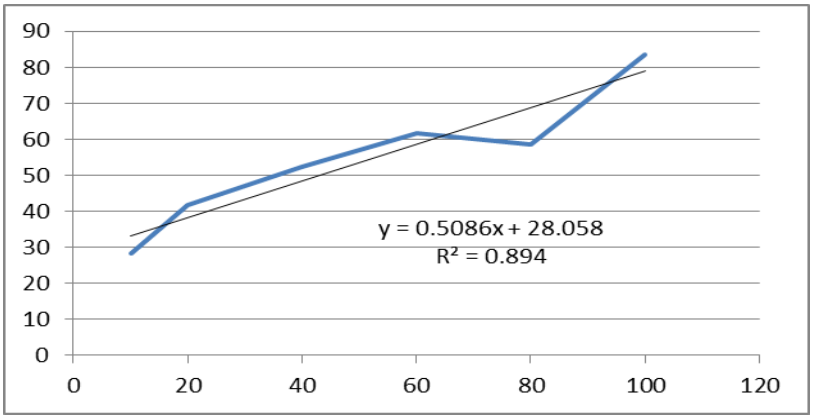

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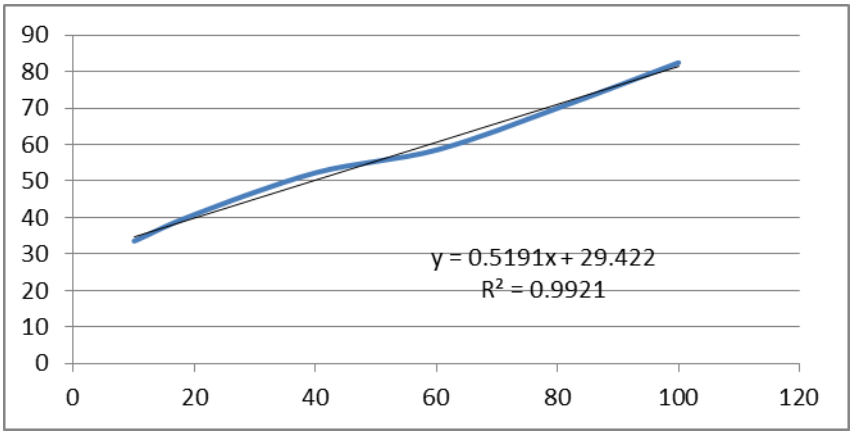
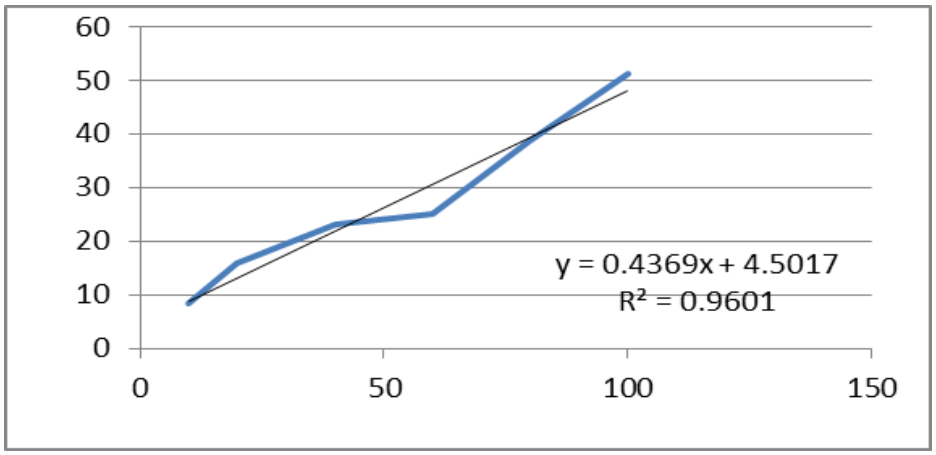
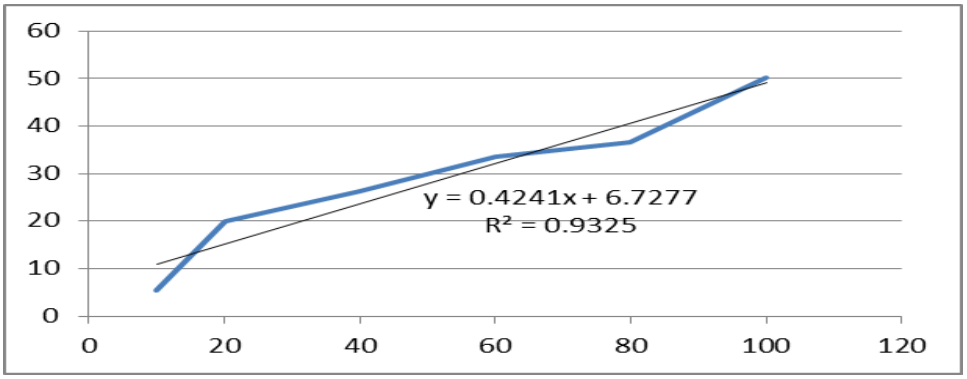


Triplicate 3

Percentage inhibition ofMRK on NO radical scavenging assay



Triplicate 1



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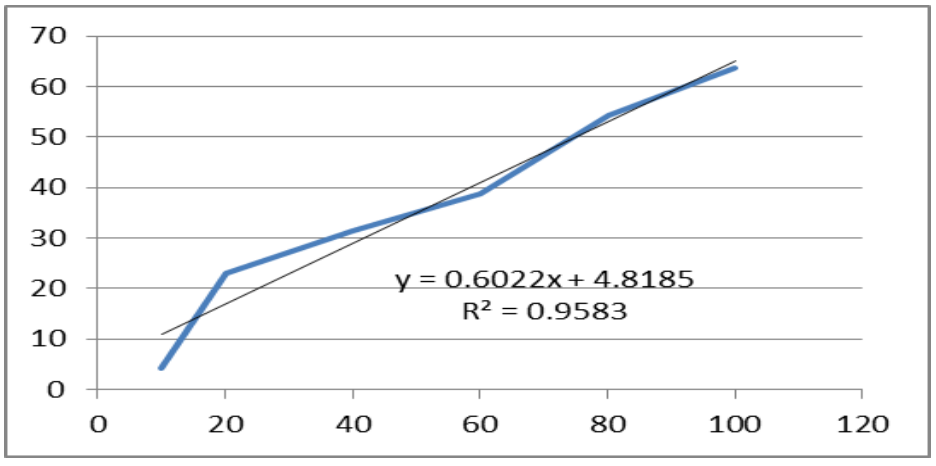


Triplicate 3

GCMS Analysis of Mega Rajanga Kirutham

GCMS- Analysis Report

GCMS (Clarus 500 Perkin – elmer (Auto system XL)), NIST Ver.2.1 MS data library

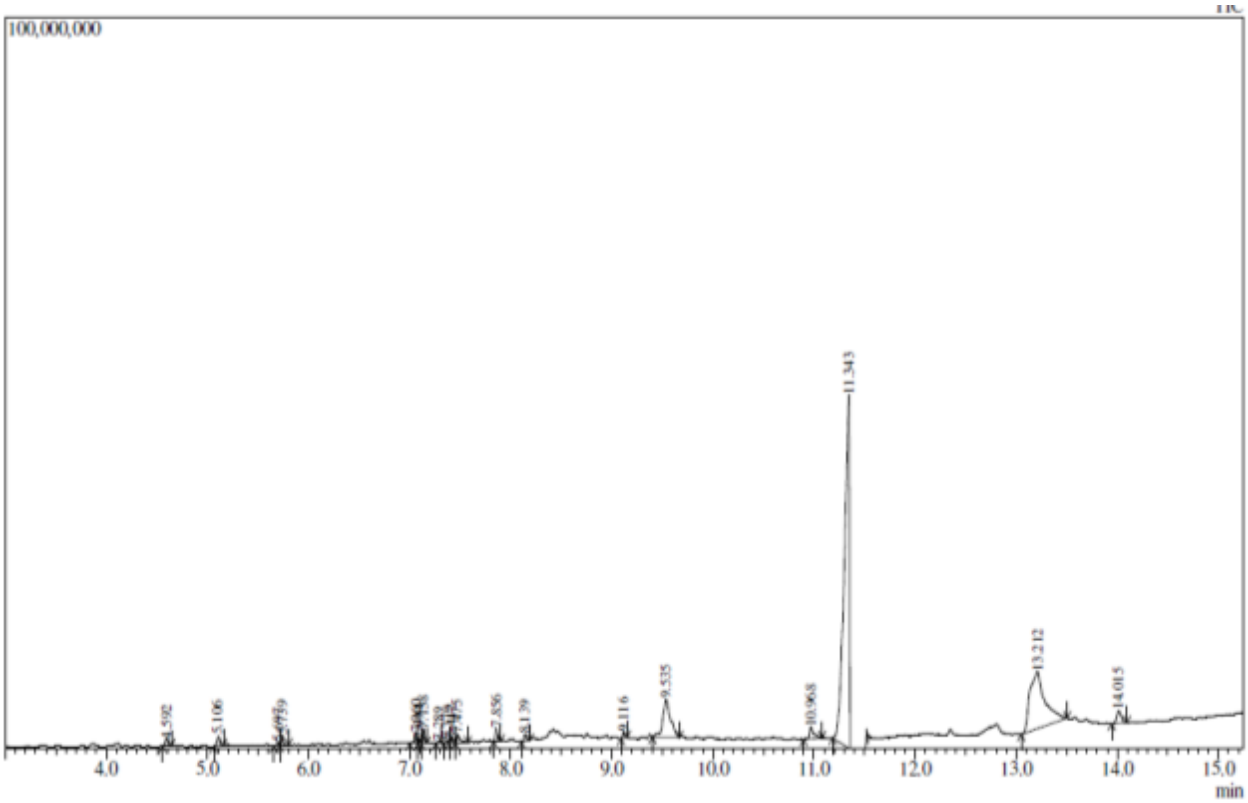
Specification:

Start Time (min)	End Time(min)	Start m/z	End m/z Scan	Speed
2.50	18.00	50.00	650.00	2000

Sample Inlet Unit: GC

GC-MS Plays a key role in the analysis of unknown components of plant origin. GC-MS ionizes compound and measures their mass numbers. Ionization method includes EI (Electron Ionization). The EI method produces ions by colliding thermal electrons emitted from a filament with sample gas molecules. This method provides high stability in ionization and obtained mass spectra show good reproducibility. The EI method provides good result for quantitative analysis as well. Quantitative analysis with GC-MS, in which only ions specific to the compounds are measured, is highly selective method without interfering components. Gas chromatography Technique involves the separation of volatile components in a test sample using suitable capillary column coated with polar or non-polar or intermediate polar chemicals. Elite-1 column (100% Dimethyl polysiloxane) is a non-polar column used for analysis of phyto-components. Elite -5 column (5% phenyl and 95% methyl polysiloxane) is an intermediate column and also used for the estimation of Phytochemical. An inert gas such as hydrogen or nitrogen or helium is used as a carrier gas .The compounds of test sample is evaporated in the injection port of the GC equipment and segregated in the column by absorption and adsorption technique with suitable GC programme.

GC-MS CHROMATOGRAM OF MRK

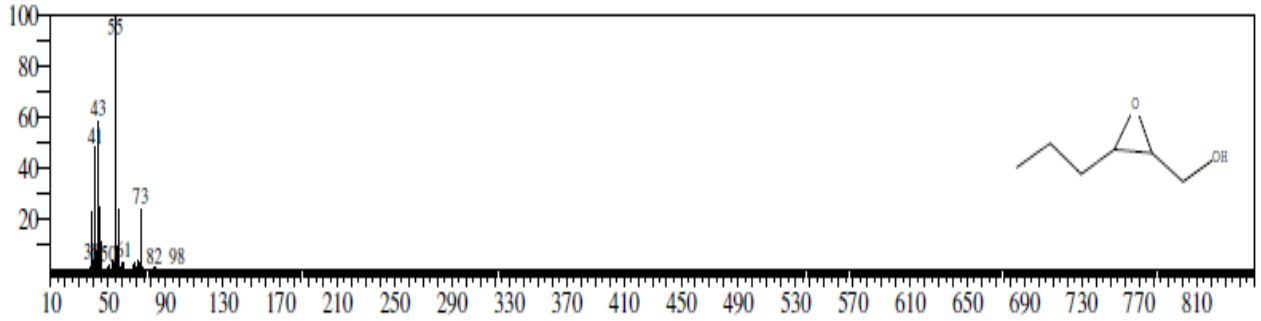


Peak Report of MRK

Peak#	R.Time	Area	Area%	Height	Height%
1	4.592	1846261	0.60	961003	1.21
2	5.106	2297040	0.74	1381496	1.75
3	5.697	822683	0.27	527310	0.67
4	5.739	2288868	0.74	1458603	1.84
5	7.060	2234139	0.72	1432391	1.81
6	7.094	850577	0.27	558522	0.71
7	7.138	2556043	0.82	1942100	2.45
8	7.289	439272	0.14	290330	0.37
9	7.370	553579	0.18	355267	0.45
10	7.412	918556	0.30	619842	0.78
11	7.475	2510721	0.81	1139567	1.44
12	7.856	2362977	0.76	1794803	2.27
13	8.139	1383561	0.45	914483	1.16
14	9.116	1231496	0.40	818231	1.03
15	9.535	27342799	8.82	5200282	6.57
16	10.968	4778323	1.54	1671578	2.11
17	11.343	169676146	54.71	48441644	61.21
18	13.212	80911899	26.09	7895814	9.98
19	14.015	5125557	1.65	1736396	2.19
		310130497	100.00	79139662	100.00

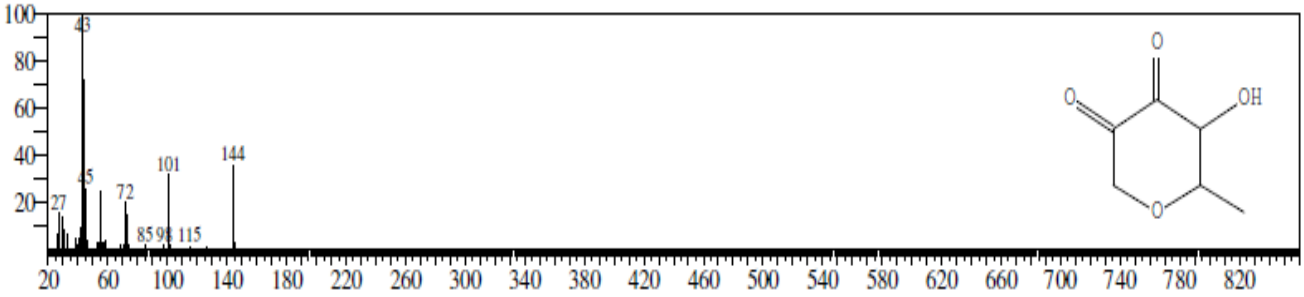
PEAK 1

Hit#:1 Entry:14765 Library:WILEY8.LIB
SI:83 Formula:C6H12O2 CAS:90528-63-5 MolWeight:116 RetIndex:0
CompName:OXIRANEMETHANOL, 3-PROPYL-, CIS- $$ (3-PROPYL-2-OXIRANYL)METHANOL # $$ (3-PROPYL-2-OXIRANYL)METHANOL $$



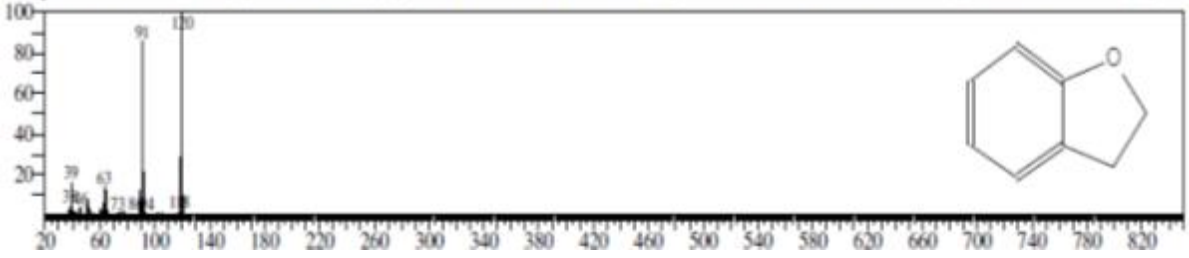
PEAK 2

Hit#:1 Entry:35082 Library:WILEY8.LIB
SI:85 Formula:C6H8O4 CAS:0-00-0 MolWeight:144 RetIndex:0
CompName:1,5-ANHYDRO-6-DEOXYHEXO-2,3-DIULOSE $$ 4H-PYRAN-4-ON, 2,3-DIHYDRO-3,5-DIHYDROXY-6-METHYL-



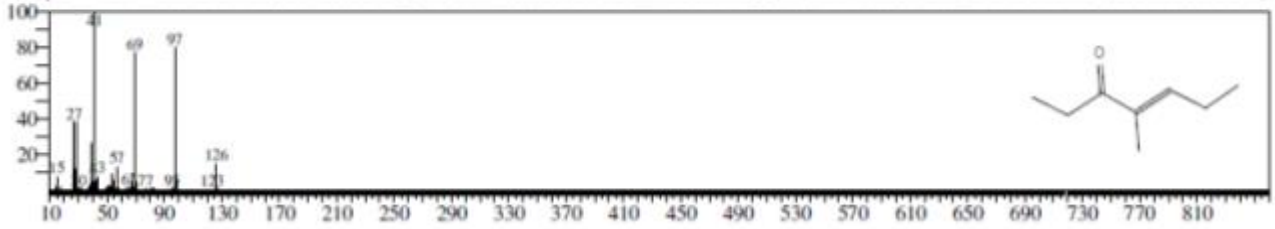
PEAK 3

Hit#:3 Entry:16666 Library:WILEY8.LIB
SI:80 Formula:C8H8O CAS:496-16-2 MolWeight:120 RetIndex:0
CompName:BENZOFURAN, 2,3-DIHYDRO- $$ 2,3-DIHYDROBENZOFURAN $$ 2,3-DIHYDRO-1-BENZOFURAN # $$ 1-BENZOFURAN $$ 2,3-D



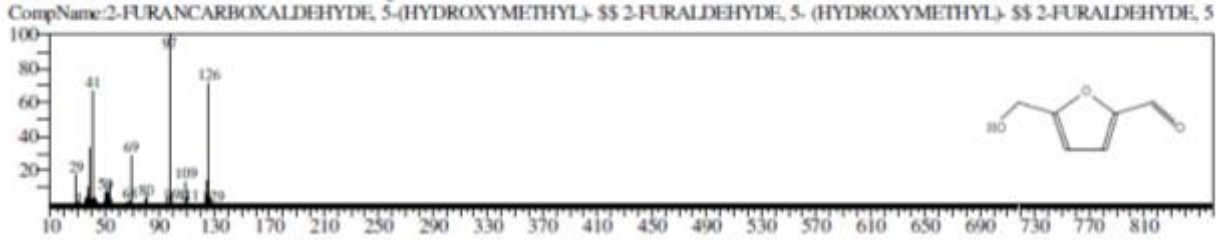
PEAK 4

Hit#:1 Entry:20177 Library:WILEY8.LIB
SI:87 Formula:C8H14O CAS:22319-31-9 MolWeight:126 RetIndex:0
CompName:4-HEPTEN-3-ONE, 4-METHYL- $$ (4E)-4-METHYL-4-HEPTEN-3-ONE # $$ (4E)-4-METHYL-4-HEPTEN-3-ONE $$ 4-METHYL-4-HEI



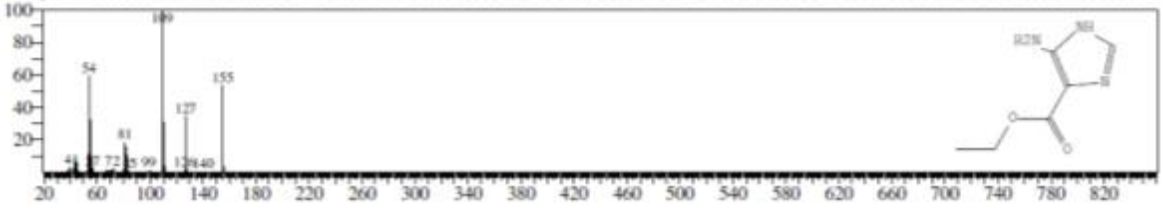
PEAK 5

Hit#:3 Entry:19684 Library:WILEY8.LIB
SI:85 Formula:C6H6O3 CAS:67-47-0 MolWeight:126 RetIndex:0
CompName:2-FURANCARBOXALDEHYDE, 5-(HYDROXYMETHYL)- $$ 2-FURALDEHYDE, 5- (HYDROXYMETHYL)- $$ 2-FURALDEHYDE, 5



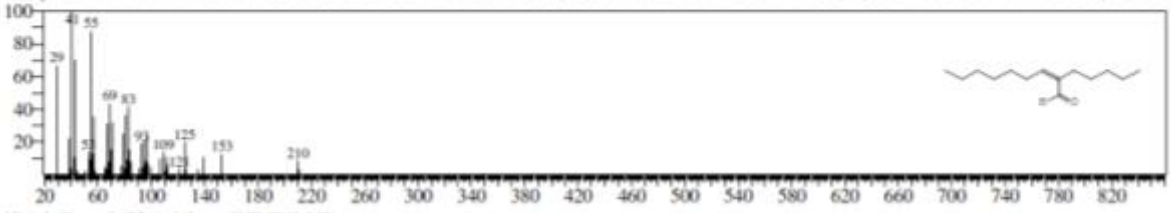
PEAK 6

Hit#:1 Entry:47671 Library:WILEY8.LIB
SI:76 Formula:C6H9N3O2 CAS:21190-16-9 MolWeight:155 RetIndex:0
CompName:ETHYL 4-AMINO-1H-IMIDAZOLE-5-CARBOXYLATE # $$ 1H-IMIDAZOLE-4-CARBOXYLIC ACID, 5-AMINO-, ETHYL ESTER $$ E



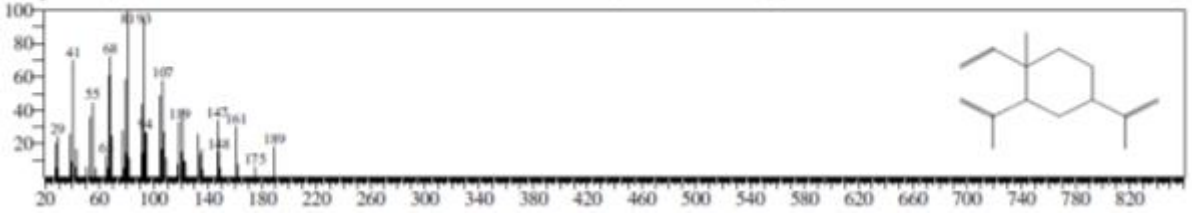
PEAK 7

Hit#:1 Entry:119123 Library:WILEY8.LIB
SI:77 Formula:C14H26O CAS:3021-89-4 MolWeight:210 RetIndex:0
CompName:2-NONENAL, 2-PENTYL- $$ 2-PENTYLNON-2-ENAL $$ (2Z)-2-PENTYL-2-NONENAL # $$ (2Z)-2-PENTYL-2-NONENAL $$ (2Z)-2-P



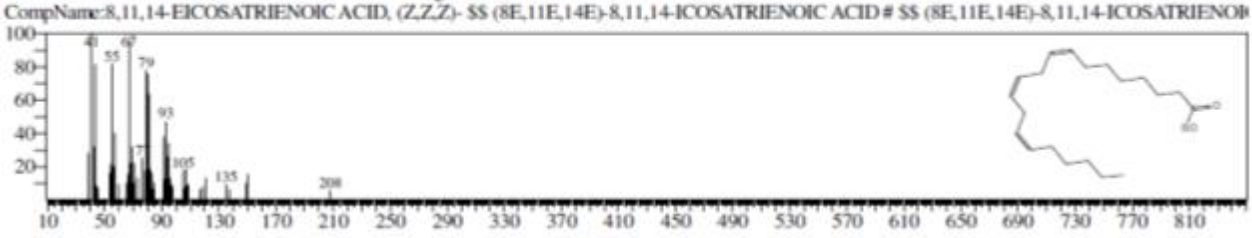
PEAK 8

Hit#:1 Entry:110359 Library:WILEY8.LIB
SI:87 Formula:C15H24 CAS:0-00-0 MolWeight:204 RetIndex:0
CompName:2,4-DIISOPROPENYL-1-METHYL-1-VINYLCYCLOHEXANE $$ BETA-ELEMEN-(2)



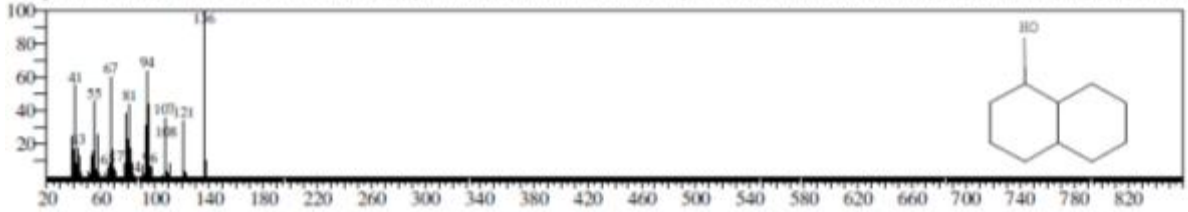
PEAK 9

Hit#:5 Entry:247628 Library:WILEY8.LIB
SI:77 Formula:C20H34O2 CAS:1783-84-2 MolWeight:306 RetIndex:0
CompName:8,11,14-EICOSATRIENOIC ACID, (Z,Z,Z)- $$ (8E,11E,14E)-8,11,14-ICOSATRIENOIC ACID # $$ (8E,11E,14E)-8,11,14-ICOSATRIENOI



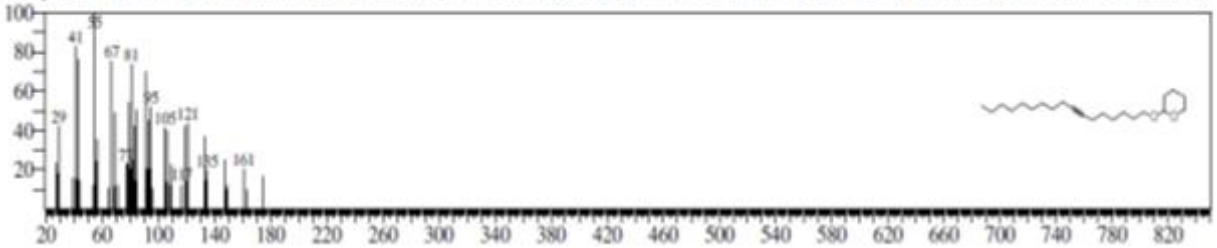
PEAK 10

Hit#:1 Entry:47270 Library:WILEY8.LIB
SI:77 Formula:C10H18O CAS:36159-47-4 MolWeight:154 RetIndex:0
CompName:1-NAPHTHALENOL, DECAHYDRO-, (1.ALPHA.,4A.BETA.,8A.ALPHA.)- $$ 1-NAPHTHOL, 1.ALPHA.,2,3,4,4A.ALPHA.,5,6,7,8,8A.BE



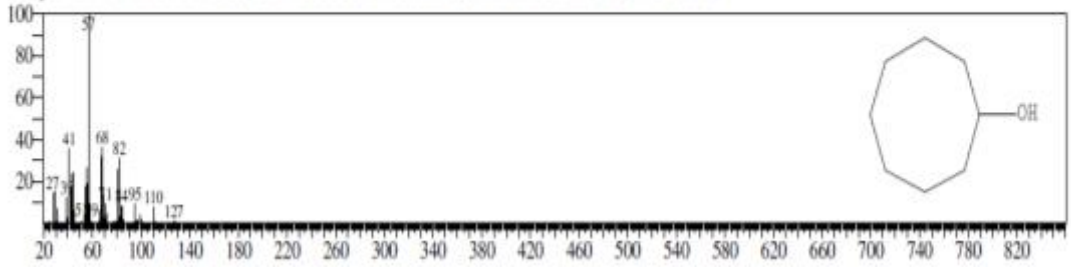
PEAK 11

Hit#:1 Entry:281428 Library:WILEY8.LIB
SI:83 Formula:C22H40O2 CAS:56599-50-9 MolWeight:336 RetIndex:0
CompName:2H-PYRAN, 2-(7-HEPTADECYNYLOXY)TETRAHYDRO- $$ 2-(7-HEPTADECYNYLOXY)TETRAHYDRO-2H-PYRAN # $$ 2(HEPTAI



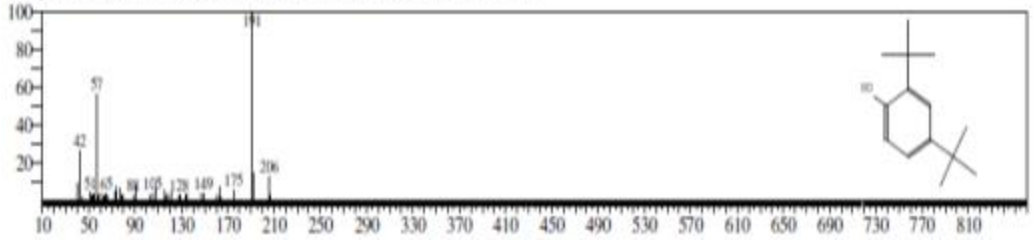
PEAK 12

Hit#:3 Entry:22253 Library:WILEY8.LIB
SI:82 Formula:C8H16O CAS:696-71-9 MolWeight:128 RetIndex:0
CompName:CYCLOOCTANOL $$ CYCLOOCTYL ALCOHOL $$ EINECS 211-800-6 $$ NSC 60162



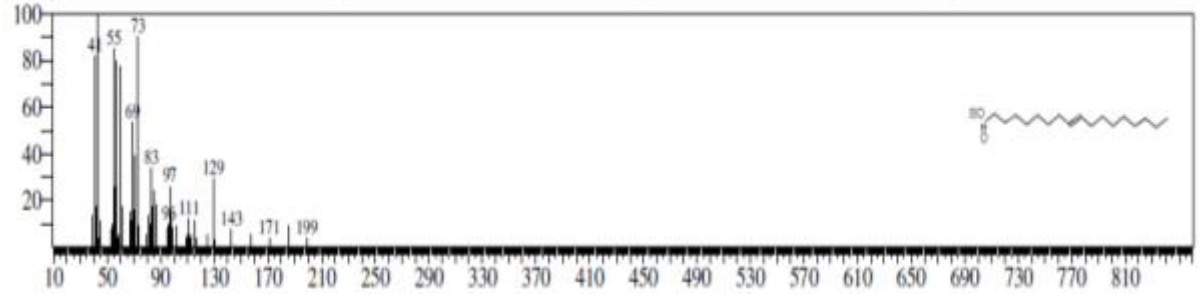
PEAK 13

Hit#:1 Entry:113154 Library:WILEY8.LIB
SI:85 Formula:C14H22O CAS:0-00-0 MolWeight:206 RetIndex:0
CompName:2,4-DITERT-BUTYLPHENOL $$ 2,4-DI-TERT-BUTYLPHENOL



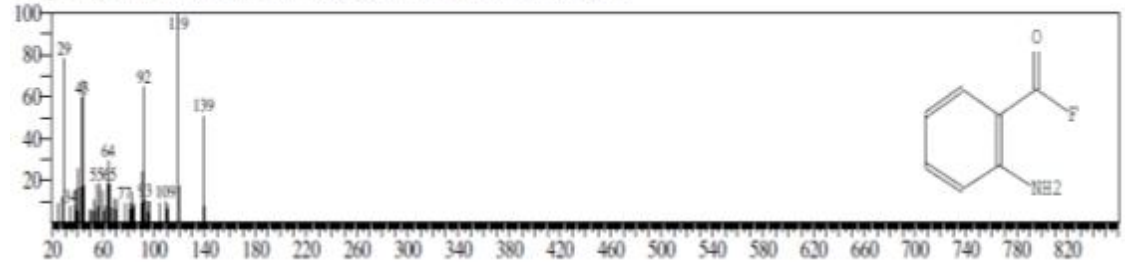
PEAK 14

Hit#:1 Entry:217532 Library:WILEY8.LIB
SI:89 Formula:C18H34O2 CAS:112-80-1 MolWeight:282 RetIndex:0
CompName:9-OCTADECENOIC ACID (Z)- $$ OCTADEC-9-ENOIC ACID $$ (9E)-9-OCTADECENOIC ACID # $$ (9E)-9-OCTADECENOIC ACID (C

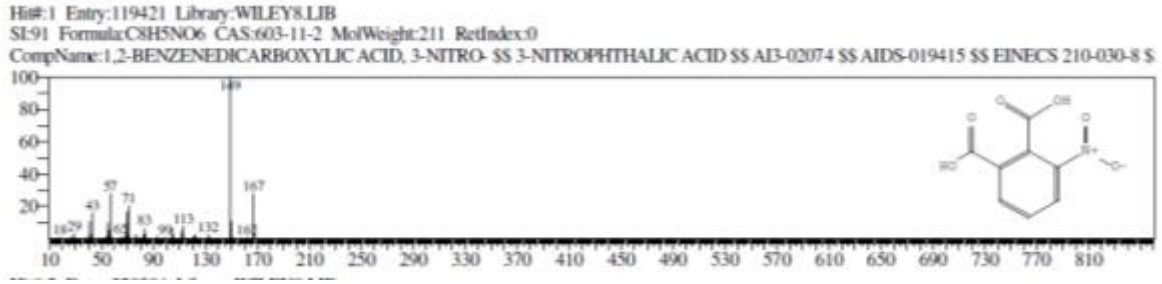


PEAK 15

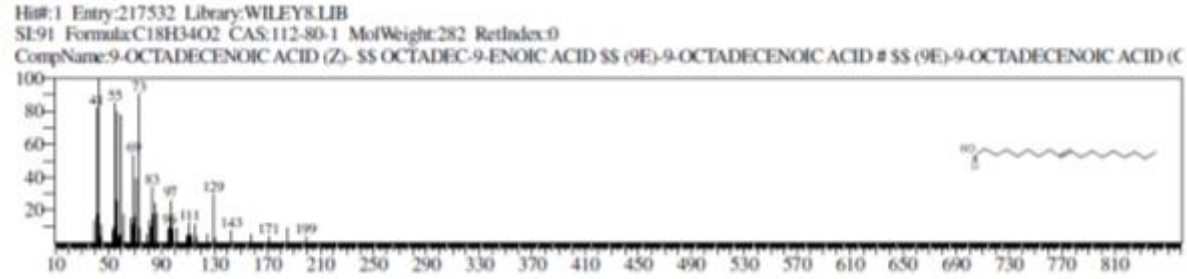
Hit#:1 Entry:30573 Library:WILEY8.LIB
SI:80 Formula:C7H6FNO CAS:39638-05-6 MolWeight:139 RetIndex:0
CompName:2-AMINOBENZOYL FLUORIDE $$ 2-AMINO-BENZOYL FLUORIDE



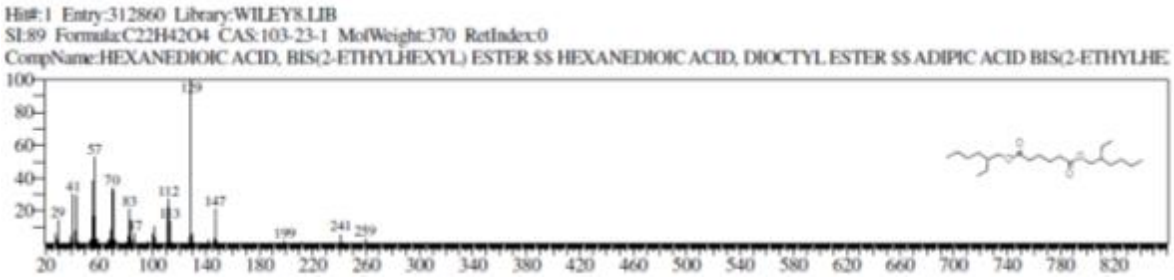
PEAK 16



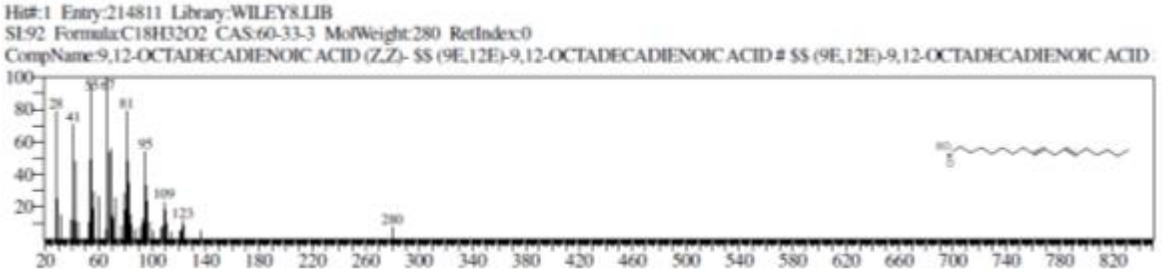
PEAK 17



PEAK 18



PEAK 19



TLC and HPTLC ANALYSIS OF MEGA RAJANGA KIRUTHAM

TLC Analysis Report

Project ID : NRS/AS/0025/02/2017

Institute : National Institute of Siddha

Sample Name : Mega rajangakritham

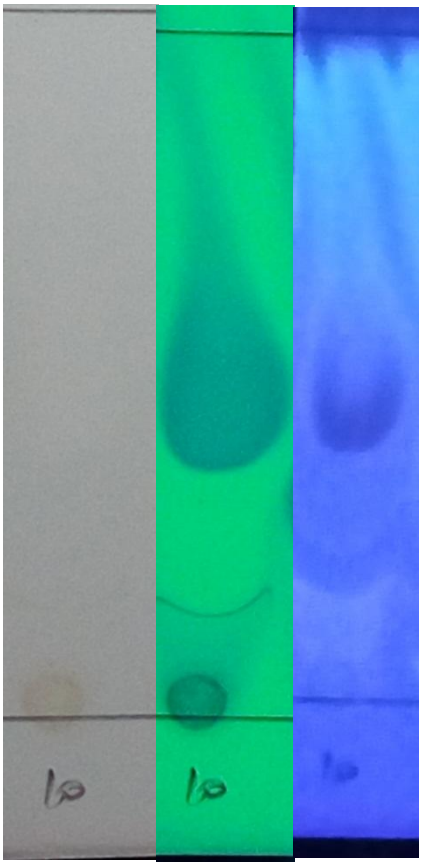
Sample ID : MRK

TLC Analysis

Test sample MRK was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Ethyl acetate: Methanol: Water (100:13.5:10) After the run plates are dried and was observed using visible lightShort-wave UV light 254nm and light long-wave UV light 365 nm

Sample Spotting

Visible Short UV Long UV



Reference

Lukasz Komsta, Monika Waksmundzka-Hajnos, Joseph Sherma . Thin Layer Chromatography in Drug Analysis .CRC Press, Taylor and Francis.

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

Reference

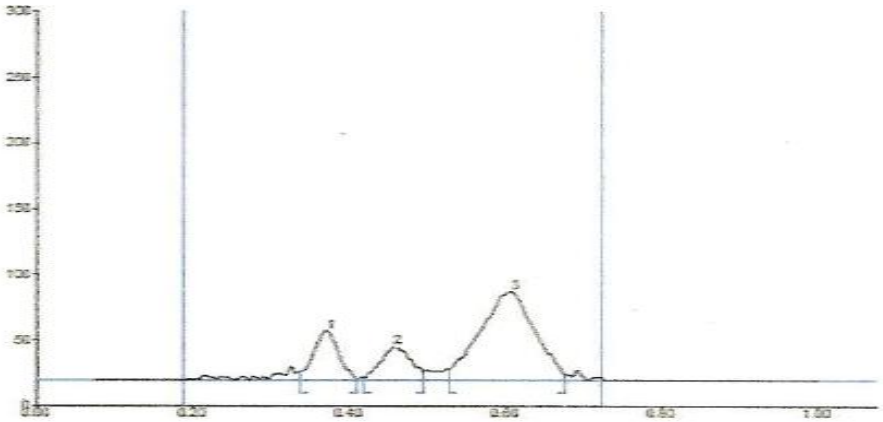
1. Wagner H. Plant Drug Analysis. A thin Layer chromatography Atlas.2nd ed. Heidelberg: Springer-Verlag Belgium; 2002:305, 227.

HPTLC Chromatographic condition

Sample	: MRK
Derivatization Solvent	: Anisaldehyde
Stationary phase	: Silica gel GF_{254}
Mobile phase	: Chloroform: Hexane: Methanol (6:3:1)
Scanning wavelength	: 366 nm
Sample concentration	: 10mg/ml
Applied volume	: 5 µl
Application mode	: CAMAG HPTLC

TLC Chromatogram

HPTLC CHROMATOGRAM OF MRK



Peak Table of HPTLC finger printing of MRK

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.34	6.0	0.37	37.3	28.62	0.41	0.6	891.4	17.19
2	0.42	1.3	0.46	25.4	19.55	0.50	6.9	749.1	14.44
3	0.53	8.7	0.61	67.5	51.83	0.68	4.2	3546.3	68.37

DISCUSSION

DISCUSSION

Vellai noi which affect the women, commonly and frequently in reproductive age group. It is one of the sexually transmitted disease. The signs and symptoms of vellai noi are correlated with Leucorrhoea in modern medicine.

40 cases of vellai noi were diagnosed based on clinical symptoms and vaginal smear. All the cases were treated in outpatient department of Ayothidoss pandithar hospital, NIS, Tambaram, Sanastorium, and Chennai-47.

The various siddha & modern methods of examination of the diseases were carried out and the data were recorded in the proforma.

The trial medicine selected for internal treatment is Mega rajanga kirutham. The day before starting the treatment with the trial drug "Mega rajanga kirutham" , Purgation was given with Meganatha kuligai-2 in hot water. Next day the patient was advised to take rest. Third day onwards the trial drug Mega rajanga kirutham-4ml twice a day before food was given continuously for 9 days. From the next day onwards the patient was under drug holiday for 9 days. Then another 9 days trial medicine was given to the patient continuously.

Before starting the treatment careful detailed history was taken and recorded for the 40 selected cases.

Laboratory investigation was done periodically for all the cases and vaginal smear were done for all the cases before and after treatment.

The biochemical, pharmacological studies of the trial drug was done in the laboratories and the results were documented.

Gender distribution:

Though vellai noi affects both sexes, only 40 female patients were selected for this dissertation. In our hospital, female cases were recorded more than the male cases. So the sexual dominance was not studied.

Age distribution:

Among 40 cases, 50% of cases were in the age between 21-30years, 45% of cases, between 31-40 years, only 5% of cases were in the age between 41-54years. So the occurrence of disease is found mostly in 21-30 years age group. (Fig: 1)

Marital status:

All the 40 cases in this study were married. Married females were more affected than unmarried because; it is a sexually transmitted disease. (Fig: 2)

Paruvakaalam:

Among 40 patients, 65% of cases were affected in Munpani kaalam. 35 % in Pinpani kaalam. (Fig: 3)

Thinai:

72.5% of the cases were coming from Neithal nilam, 25% came from Marytham. Only 2.5% were coming from Kurini. Maximum No of cases were from the Neithal nilam. Because Vellai noi is a Pitha disease, and people who are living in sea sour (Neithal nilam) are more prone to pitha disease. (Fig: 4)

Diet factors:

Among 40 cases, 97.5% cases were Non-vegetarians. Only 2.5% were vegetarians. Most of the cases were found in non-vegetarian category. In non-vegetarian people, body heat is increased so it may be produce pitha disease. (Fig: 5)

Socio-economic Status:

Among 40 cases, 45% of cases were belongs to poor class, 40% were brlonging to middle class. Only 12.5 % were in rich people. So this disease was found mostly in poor class people due to poor socio-economic stage, poor hygiene and ignorance of treatment. (Fig: 6)

Family history:

Among 40 cases, 90% of cases were not found any family history; only 10% of cases had family history of vellai noi. (Fig: 7)

Kaalam:

Among 40 cases, 72.5% of patients were affected in vatha kaalam (age up to 33years). 27.5% of patients were affected in Pitha kaalam (34 to 66 years). (Fig: 8)

Habit:

All the 40 cases do not have any bad habits like Pan, Snuff etc.

Thegi:

Among 40 cases, 37.5% of patients are Pitha thegi, and 30% are Vatha thegi, 32.5% are Thontha thegi. Most of the cases were Pitha thegi category; they are more prone to pitha disease. (Fig: 9)

Educational Status:

Among 40 cases, 40% of patients are illiterate, 27.5% are middle school completed, 20% are High school completed and 12.5% are Degree holder. Illiterate people were mostly affected, due to poor hygiene, ignorance of treatment. (Fig: 10)

Body built:

Among 40 cases, 55% of patients were under weight. 27.5% were Normal weight and 17.5% were Obese. (Fig: 11)

Occupation:

Among 40 cases, 50% of patients were in daily wages. 37.5% of patients were housewives. Only 12.5% of patients were in sedentary work. (Fig: 12)

Treatment History:

Among 40 cases, 45% of patients had allopathic treatment for Leucorrhoea. 20% of patient's dose not had any treatment for leucorrhoea. 17.5% of patients had siddha treatment, 7.5% had Ayurvedhic and 10% had Homeopathic treatment for the same illness. (Fig: 13)

Clinical history:

100% of patients had whitish/yellowish discharge per vagina, Low back pain, vulval irritation, and Dyspareunia. 97.5% had Pruritus vulva, 95% had lower abdominal pain and 75% had Dysuria. (Fig: 19)

Disturbances of Vatham:

All the 40 cases were affected with Abanan, Viyanan, Samanan and Devathathan.

Affected abanan produce vaginal discharge.

Affected viyanan produce low back pain and lower abdominal pain.

Affected devathathan produce tiredness and general weakness of upper limb and lower limb. (Fig: 14)

Disturbances of Pitham:

Among 40 cases, 50% of patients were affected with Anarpitham, 20% of cases were affected with Ranjaga pitham. Only 5% of cases were affected with Alosaga pitham.

Affected anarpitham produce loss of appetite and ranjaga pitham produce Anaemia. (Fig: 15)

Disturbances of Kabam:

Among 40 cases 100% of patients were affected with Avalambagam and santhigam.

Affected santhigam produce Low back pain. (Fig: 16)

Changes in Kosangal:

Among 40 cases, 100% of patients were affected with Annamaya kosam and Manomaya kosam. 80% of patients were affected with piranamaya kosam. 55% of cases were affected with Anandhamaya kosam.

Affected Annamaya kosam indicates loss of appetite, general weakness, and tiredness.

Affected Manomaya kosam indicates Stress due to increased vaginal discharge.

Affected piranamaya kosam indicates low back pain and weakness in both upper limb and lower limb.

Affected Ananthamaya kosam indicates Disturbed Sleep due to pruritus vulva. (Fig: 17)

Seven Udal thathukkal:

Among 40 cases 100% of patients were affected with saaram and suronitham. 30% of patients were affected with enbu. 20% of patients were affected with senneer.

Affected saaram indicates general weakness and tiredness.

Affected suronitham indicates excessive vaginal discharge.

Affected enbu indicates low back pain both upper limb and lower limb pain. (Fig: 18)

Neerkkuri and Neikkuri:

55% of case of Neikkuri showed pitha neer, 25% showed kaba neer and 20% of cases showed slowly spread shape. Most of the neikkuri showed pitha neer because it indicates increased pitham in these patients.

Special investigation:

VDRL, vaginal smear tests were done in all cases before treatment. All the cases had negative VDRL test.

Among 40 cases only 15 cases were Wet test positive for Trichomonas vaginalis. Another 25 cases were symptomatically treated with this trial drug. After treatment among 15 positive cases, 10 cases were turned to negative result. (Fig: 20)

Results after treatment:

66% of cases showed negative result for Trichomonas vaginalis. Symptomatically among 40 cases 50% of cases showed good result 40% of cases showed moderate improvement. Only 10% of cases showed poor result. (Fig: 21)

Chemical Analysis:

The chemical study of the trial drug reveals Calcium, Carbonate, Iron, Zinc, Magnesium, Alkaloid and Tannic acid.

Pharmacological study:

The pharmacological study reveals the trial drug have Anti inflammatory, Anti microbial and Anti oxidant activity in In vitro study.

Physico-chemical, Phyto chemical, GCMS, TLC, and HPTLC has also be done for trial drug.

STATISTICAL ANALYSIS

Statistical analysis for Clinical study

All collected data were entered into MS Excel software using different columns as variable and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired't' test was performed for determining the significance between before and after treatment.

Paired Sample Statistics (Symptoms score before and after treatment)

Variable	**Obs**	**Mean±std**	**'t' Value**	**p Value**
Before treatment	40	6.65±0.53	17.13	<0.0001
After treatment	40	1.57±1.75		

The Mean ± Standard deviation of symptom score at before and after treatment were 6.65±0.53 and 1.57±1.75 respectively which is highly significant. (t value = 17.13, p = 0.0001).

Paired Sample Statistics (Total cell count before treatment and after treatment)

Variable	**Obs**	**Mean±std**	**'t' Value**	**p Value**
Before treatment	**40**	**7710±2104**	**1.97**	**0.054**
After treatment	**40**	**7242±1598**		

The Mean ± Standard deviation of TC count at before and after treatment were 7710±2104 and 7242±1598 respectively which is moderately significant. (t value =1.97, p = 0.054).

Paired Sample Statistics (LDL before and after treatment)

Variable	**Obs**	**Mean±Std**	**'t' Value**	**p Value**
Before treatment	**40**	**81.675±16.03**	**2.3316**	**0.0125**
After treatment	**40**	**2.598±16.43**		

The Mean ± Standard deviation of LDL at before and after treatment were 81.675±16.03 and 2.598±16.43 respectively which is moderately significant. (t value =2.3316, p = 0.0125).

SUMMARY

Summary

- The Aim of the study is to evaluate the efficacy of Mega rajanga kirutham in Vellai noi.
- The protocol of this study has been submitted to IEC of NIS on 26-8-2015 and then approval was got from IEC for conducting this clinical study. **The IEC NO is NIS/IEC 9/2014-15/8-26.08.2015.**
- This Clinical study was registered in Clinical Trial Regisry of India on 7-3-17. And the **CTRI NO is CTRI/2017/03/008025.**
- In the period of seven months, 250 cases were screened for this clinical study. Only 17 cases were identified as Trichiomoniasis by using Wet test, all the other cases were Negative, but the clinical symptoms are nearly correlated with Trichomoniasis. So as per our HOD guidance I had taken other negative cases with clinical symptoms for this study.
- For this clinical study, 40 cases were selected based on the inclusion and exclusion criteria. All the cases were treated in OPD of Department of Maruthuvam, Ayothidoss pandithar hospital, National institute of Siddha, Chennai-47.
- Clinical diagnosis of vellai noi was done by siddha and modern methodology.
- Blood, Urine Investigations and Vaginal smear test were carried out before and after treatment and data were recorded in the Lab investigation Form.
- The day before starting treatment with the trial drug “Mega rajanga kirutham”, purgation was given with Meganatha kuligai-2 in hot water at early morning.
- The second day, after purgative therapy the patient was advised to take rest. Third day onwards the trial drug “Mega rajanga kirutham -4ml twice a day, before food was given continuously for 9 days.
- From the next day onwards the patient was under drug holiday for 9 days. Then another 9 days trial medicine was given to the patient continuously.
- During the study period , there were no adverse reactions reported
- The chemical analysis of the trial drug reveals Calcium, Carbonate, Iron, Zinc, Magnesium, Alkaloid and Tannic acid.
- The pharmacological study reveals the trial drug have Anti inflammatory, Anti microbial and Anti oxidant activity in In Vitro studies.

- Physico-chemical, Phyto chemical, GCMS, TLC, and HPTLC has also be done for trial drug. There is no harmful chemical was identified.
- Statistical analysis: There is significant difference between clinical symptoms score of before and after treatment ($p<0.0001$).
- The improvements of the patients were observed and clinical assessments were noted in a weekly progress chart. Observation of both clinical and laboratory parameters before and after treatment ensures the efficacy of the trial drug.
- The outcome of this study reveals that out of 17 positive cases, 10 cases showed negative result for Trichomonas vaginalis in after treatment, 2 cases were withdrawal from this study andsymptomatically among 40 cases, 50% of cases showed good result 40% of cases showed moderate improvement. Only 10% of cases showed poor result.

CONCLUSION

A. Clinical study reveals that the trial drug showed good improvement in 50% of cases. Moderate improvement in 40% of cases. Poor improvement in 10% of cases. There were no adverse effects found inall treated cases during the course of the treatment. Hence the drug is effect in the treatment of Leucorrhoea.
B. The Pharmacological study revealed the trial drug had Anti inflammatory, Anti microbial and Anti oxidant activity.
C. Physico chemical, Phyto chemical, GCMS, TLC and HPTLC analysis showed phytoconstituents which is responsible for therapeutic action.
D. Because of the encouraging clinical and laboratory results, the study may be extended with the same drug in more number of cases, in treating Vellai noi successfully.

ANNEXURE

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of TrialCTRI No	CTRI/2017/03/008025 [Registered on: 07/03/2017] Trial Registered Prospectively
Acknowledgement Number	REF/2016/06/011472
Last Modified On:	06/03/2017
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug Siddha
Study Design	Single Arm Trial
Public Title of Study Clarification(s) with Reply Modification(s)	Clinical evaiuation of siddha drug Mega rajangakirutham in the treatment of Leucorrhoea (vellainoi)
Scientific Title of Study Clarification(s) with Reply Modification(s)	Clinical evaluation of Mega rajangakirutham in the treatment of vellainoi(Leucorrhoea)
Acronym	Mega rajangakirutham
Secondary IDs if Any	Secondary ID: NIL; Identifier: NIL
Details of Principal Investigator or	Name: Dr S SANTHANAKITTU Designation: PG SCHOLAR

overall Trial Coordinator (multi-center study)	Affliation	National institute of siddha
	Address	Department of maruthuvam, National institute ofsiddha, Tambaram sanatorium, Kancheepuramdist chennai-600047, Tamilnadu, India Department of Maruthuvam, National institute of Siddha, Tambaram sanatorium, Kancheepuram, Chennai-47 Kancheepuram TAMIL NADU 600047 India
	Phone	9952410979
	Fax	
	Email	drsakisivan23@gmail.com
Details Contact Person Scientific Query	Name	Dr N PERIASAMY PANDIAN
	Designation	Associate professor.
	Affliation	National institute of siddha
	Address	Natioriumnal institute of siddha, Tambaramsanatorium, chennai-47, Natioriumnal institute of siddha, Tambaramsanatorium, chennai-47, Kancheepuram TAMIL NADU 600047 India
	Phone	9884878469
	Fax	044-22381314
	Email	periasamypandian22@gmail.com
Details Contact Person Public Query	Name	Dr H VETHA MERLIN KUMARI
	Designation	LECTURER
	Affliation	National institute of siddha
	Address	Natioriumnal institute of siddha, Tambaramsanatorium, chennai-47, Natioriumnal institute of siddha,

	Tambaramsanatorium, chennai-47, Kancheepuram TAMIL NADU 600047 India
Phone	9894782366
Fax	044-22381314
Email	dr.vetha@gmail.com

Source of Monetary or Material Support

AY0THIDOSS PANDITHAR HOSPITAL

Primary Sponsor	
Name	Ayothidosspandithar hospital
Address	NATIONAL INSTITUTE OF SIDDHA, TAMBARAM SANATORIUM CHENNAI-47
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor	
Name	Address
NIL	NIL

Countries of Recruitment
India

Sites of Study
Clarification(s) with Reply
Modification(s)

No of Sites = 1			
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr S Santhanakittu	AYOTHIDOSS PANDITHAR HOSPITAL	OPD NO 1 Department of maruthuvam National institute of siddha, Tambaram	9952410979 drsakisivan23@gmail.com

			sanatorium, Chennai-47. Kancheepuram TAMIL NADU	

Details of Ethics Committee Modification(s)

No of Ethics Committees= 1				
Name of Committee	Approval Status	Date of Approval	Approval Document	Is IEC?
Institutional Ethics Committee	Approved	26/08/2015	Approval File	No

Regulatory Clearance Status from DCGI

Status	Date	Aproval Document
Not Applicable	No Date Specified	No File Uploaded

Health Condition / Problems Studied

Health Type	Condition
Patients	VELLAI NOI(LEUCORRHOEA)

Intervention / Comparator Agent

Type	Name	Details
Intervention	MEGA RAJANGA KIRUTHAM(INTERNAL)	4 ml of Megarajangakirutham administered orally twice a day for a period of 9 days twice a month.
Comparator Agent	NIL	NIL

Inclusion Criteria

Age From	21.00 Year(s)
Age To	45.00 Year(s)
Gender	Female
Details	• Married female,

	• Patient having the symptoms of whitish or yellowish discharge per vagina, • Pruritis vulva, vulval irritation, dysuria, abdominal pain, low backache • Patient who is willing to cooperate for vaginal swab examination & who undergo routine blood investigation. • Positive Wet test for Trichomonasvaginalis • Patient who is willing to participate in trial and signing in consent form
Exclusion Criteria	Details: • Cases not confirmed by Wet test for Tr.vaginalis. • H/O Diabetes mellitus • H/O Bacterialvaginosis/Vulvovaginal candidiasis • H/O Sexually transmitted disease (syphilis, HIV, gonorrhoea) • H/O Non-specific leucorrhea • Pregnancy and lactation • H/OMalignancy
Method of Generating Random Sequence	Not Applicable
Method of Concealment	Case Record Numbers
Blinding/Masking	Open Label
Primary Outcome Clarification(s) with Reply Modification(s)	Outcome: 1) It is assessed by the vaginal smear when wet test becomes negative for Trichomonasvaginalis after treatment, 2) reduction of clinical symptoms such as white or yellowish discolouration per vagina, lower abdominal pain, low back pain, pruritus vulva, foul smell,dysuria and dispareunia. TimePoints: 27 days.

Secondary Outcome Clarification(s) with Reply Modification(s)	<table><tr><th>Outcome</th><th>TimePoints</th></tr><tr><td>1)Socio economic status 2) Age related to the disease will be assessed.</td><td>27 days</td></tr></table>
Target Sample Size	Total Sample Size="40" Sample Size from India="40"
Phase of Trial	Phase 3
Date of First Enrollment (India) Clarification(s) with Reply Modification(s)	15/03/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	Years="0" Months="6" Days="0"
Recruitment Status of Trial (Global) Clarification(s) with Reply Modification(s)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details Clarification(s) with Reply Modification(s)	NONE YET
Brief	It is a single non-randomized, open -labe trial to determine

Summary	the efficacy of MEGA RAJANGA KIRUTHAM (prepared from herbal constitutents) in patients with Vellainoi(Leucorrhoea). In this trial 40 patients will be recruited and the trial drug will be administered 4 ml twice a day for a period of 9 days twice a month. During the trial period if any AE/SAE/SUSAR will be noticed and referred to pharmacovigilancedept in NIS and further management will also be given in NIS OPD /IPD. The entire trial will be monitored by the research monitoring committee of NIS. During this trial all the safety efficacy parameters will be recorded in the CRF. After completion of the trial all the study related data will be analysed statistically. The out come of this trial will be published in Indian Journal of Medical Research.

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान
Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE
आयुष विभाग - स्वास्थ एवं परिवार कल्याण मंत्रालय
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फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in
वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16

Dt: 05.10.2015

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.S.Santhanakittu, **Department of Maruthuvam**	
Protocol title: Clinical evaluation of siddha drug MEGARAJANGA KIRUTHAM in the treatment of VELLAI NOI.	
Documents filed	1) Protocol, 2) Data Collection forms 3) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	**Yes**
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/9/2014-15/8 – 26.08.2015**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

Chairman

Member Secretary

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation "**Mega Rajanga Kirutham**" (Internal) for Vellai Noi taken up for Post Graduation Dissertation studies by **Dr.S.Santhanakittu**, M.D.(S), II year, Department of Maruthuvam, 2016, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology, Micromorphology and Taxonomical methods as

Ficus racemosa Linn. (Moraceae), Bark

Syzygium cumini Linn. (Myrtaceae), Bark

Lannea coromandelica (Hout.) Merrill (Anacardiaceae), Stem bark

Saccharum officinarum Linn. (Poaceae), Stem juice.

Phyllanthus emblica Linn. (Euphorbiaceae), Fruit juice

Citrus limon (Linn.) Burm. f. (Rutaceae), Fruit

Sesamum indicum Linn. (Pedaliaceae), Seed oil

Taxus baccata Linn. (Taxaceae), Leaf

Elettaria cardamomum Maton (Zingiberaceae), Fruit

Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Myrtaceae), Flower bud

Myristica fragrans Houtt. (Myristicaceae), Seed

Alpinia officinarum Hance (Zingiberaceae), Rhizome

Glycyrrhiza glabra Linn. (Fabaceae), Root

Curculigo orchioides Gaertn. (Amaryllidaceae), Rhizome

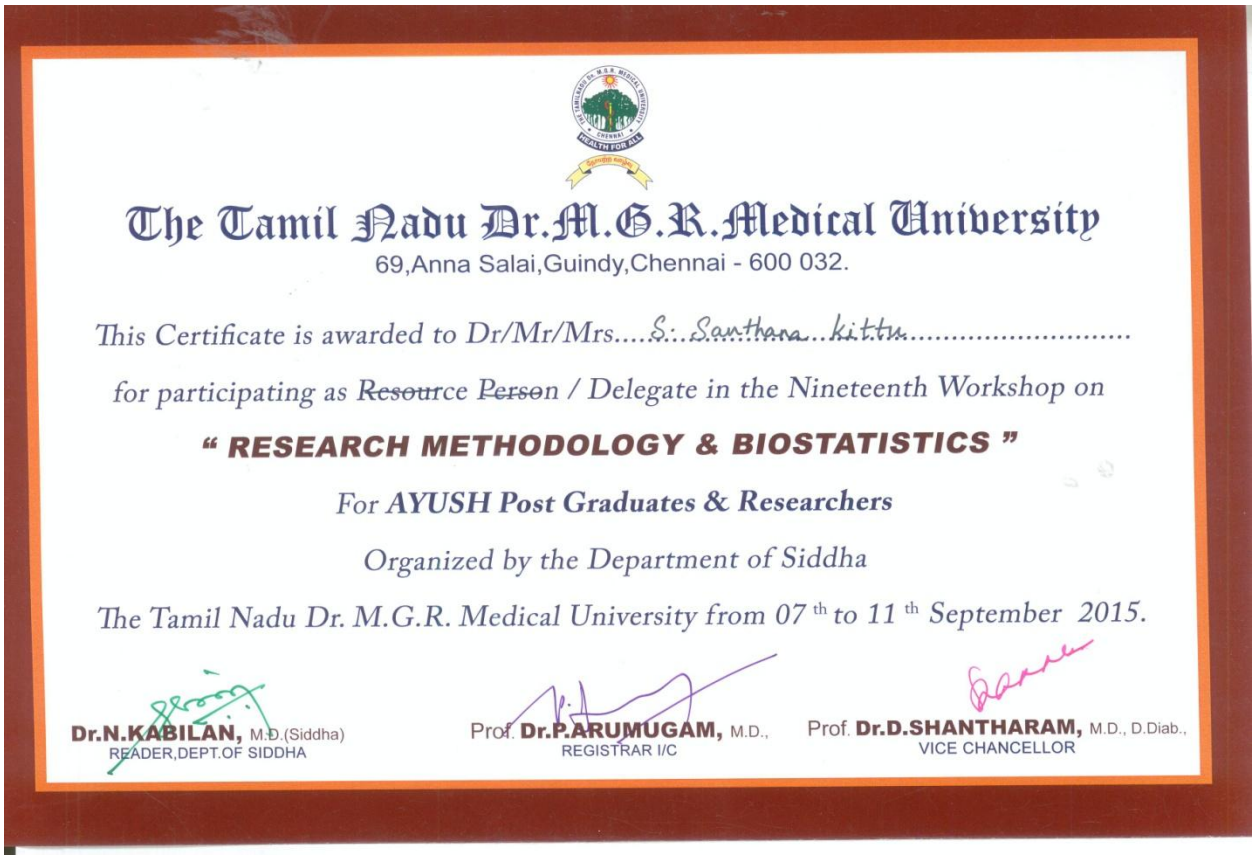
MEDICINAL BOTANY CHENNAI 600 047 National Institute of Siddha

Certificate No: NISMB2252016

Date: 23-4-2016

Authorized Signatory

Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA



The Tamil Nadu Dr.M.G.R.Medical University

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....S. Santhana kittu.....

for participating as ~~Resource~~ ~~Person~~ / Delegate in the Nineteenth Workshop on

" RESEARCH METHODOLOGY & BIOSTATISTICS "

For ***AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 07 th to 11 th September 2015.

Dr.N.KABILAN, M.D.(Siddha)
READER,DEPT.OF SIDDHA

Prof. **Dr.P.ARUMUGAM,** M.D.,
REGISTRAR I/C

Prof. **Dr.D.SHANTHARAM,** M.D., D.Diab.,
VICE CHANCELLOR

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E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Date: 24.03.2017

To,

Dr.S.Santhana Kittu
National Institute of Siddha
Tambaram Sanatorium, Chennai - 600 047, Tamil Nadu, India.

Project Id : **NRS/AS/0025/02/2017**

This is to certify that Dr.S.Santhana Kittu from National Institute of Siddha, Chennai has carried out the following activity at our facility for the trial drug *Mega rajanga kritham (MRK)*

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Mega rajanga kritham (MRK)*	I
2.	In-vitro Anti-Inflammatory Activity *Mega rajanga kritham (MRK)* by Protein (Albumin) denaturation Assay	II
3.	Evaluation of In-Vitro anti-oxidant potential of *Mega rajanga kritham (MRK)* by NO, DPPH and ABTS Assay	III
4.	In-vitro Anti-microbial activity of *Mega rajanga kritham (MRK)* by Disc Diffusion Method	IV

Note:

- *Annexures was attached as a separate enclosure along with this report.*

NOBLE RESEARCH SOLUTIONS TAMIL NADU INDIA CHENNAI

HITECH DIAGNOSTIC CENTRE

The Extra Care Lab

No.935, GKS Tower, Poonamallee High Road, Purasawalkam, Chennai - 600 084

An ISO 9001:2008 Certified Organisation

Patient :P0577462 **Mrs. JEYALAKSHMI (34/F)**

SID.No. :**082928**

Branch :**TAMBARAM**

Referrer :**Dr.SANTHANA KITTU . S**

Ph :9094953538

Date :28/12/2016

Rec Time :09:31:24

Rpt Date :28/12/2016

Rpt Time :17:50:51

Page # :1 / 1

Re-print

Test	Result	Biological Reference Interval

TEST REPORT

MICROBIOLOGY

VAGINAL SMEAR FOR TV & GC	: Trichomonas vaginalis seen. No Gonococci seen.	

DR.SP.GANESAN. MBBS.,DCP.,

*** End Of Report ***

" Our Kilpauk Lab Serves You Round The Clock "

Dr. SP. Ganesan, MBBS,DCP,eMBA Medical Director | Dr. Radhi Lawrence, Chief Pathologist | Dr. Pooja Raghavan, MBBS,DCP, Clinical Pathologist | Dr. V. Priya, MD Consultant Microbiologist | Mrs.Malini Parasuraman, M.Sc, M.phil Chief of Lab Services

a Unit of Dr. Ganesan's Hitech Diagnostic Centre Pvt. Ltd.

P.T.O

HITECH DIAGNOSTIC CENTRE

The Extra Care Lab

No.935, GKS Tower, Poonamallee High Road, Purasawalkam, Chennai - 600 084

An ISO 9001:2015 Certified Organisation

Patient : P0586802 **Mrs. JEYALAKSHMI (34/F)**

SID.No. : **008780**

Branch : **TAMBARAM**

Address :

Ph :9094953538

Date :08/02/2017

Rec Time :11:31:43

Rpt Date :08/02/2017

Rpt Time :20:04:19

Page # :1 / 1

Final report

Referrer : **Dr.SANTHANA KITTU . S**

Test	Result	Biological Reference Interval

TEST REPORT

MICROBIOLOGY

VAGINAL SMEAR FOR TV & GC : No TV or GC seen. Few pus cells, Many Gram negative bacilli were seen.

Ganesan

DR.SP.GANESAN. MBBS.,DCP.,

*** End Of Report ***

" Our Kilpauk Lab Serves You Round The Clock "

Dr. SP. Ganesan, MBBS,DCP,MIMA Medical Director | Dr. Radhi Lawrence, MD (path) Chief Pathologist | Dr. Pooja Raghavan, MBBS,DCP Clinical Pathologist | Dr. V. Priya, MD Consultant Microbiologist | Mrs Malini Parasuraman, M.Sc, M.phil Chief of Lab Services

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P.T.O

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

Clinical Evaluation of Siddha drug "MEGA RAJANGA KIRUTHAM" (Internal) in "VELLAI NOI (LEUCORRHOEA) FORM l - SCREENING AND SELECTION PROFORMA

OP NO: NAME: …… AGE: ……GENDER: …

OCCUPATION: ……

ADDRESS:

CONTACT NO:

INCLUSION CRITERIA

- Age:21-45 yrs Yes / No
- Married female Yes / No
- Patient having the symptoms of whitish or yellowish discharge per vagina, Yes / No
- Pruritis vulva, vulval irritation, dysuria, abdominal pain, low backache Yes / No
- Patient willing to cooperate for vaginal swab examination Yes / No
- Patient willing to undergo routine blood investigation Yes / No
- Positive Wet test for Trichomonas vaginalis Yes / No
- Patient willing to participate in trial and signing in consent form Yes /No

EXCLUSION CRITERIA:

- History of Diabetes mellitus Yes / No
- History of Bacterial vaginosis/Vulvovaginal candidiasis Yes / No
- History of STD (Syphilis,HIV,gonorrhoea) Yes / No
- History of non specific leucorrhea Yes / No
- Pregnancy and lactation Yes / No
- History of Malignancy Yes / No

ADMITTED TO TRIAL

YES ☐ NO ☐

If Yes Serial NO: ☐☐

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD:**

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSSPANDITHARHOSPITAL
DEPARTMENT OF MARUTHUVAM

Clinical evaluation of siddha drug"MEGA RAJANGA KIRUTHAM" (Internal) in "VELLAI NOI (LECORRHOEA)" **FORM II- CASE RECORD FORM**

1. STUDY NO ---------- 2. OP/IP NO ---------- REG NO:

3. NAME ---------- 4. . Age (years): _____ Height: ____ m Weight: _____ Kg5)

5. Educational Status:

1) Literate ☐ 2) Illiterate ☐

6. Occupation:

7. Marital Status: 1.Married ☐ 2 .Unmarried ☐

If married; Gravidity ☐ Parity ☐

Dyspareunia - Present ☐ Absent ☐

8. Complaints and Duration:

_____

_____

_____

MENSTRUAL HISTORY

1.Age at menarche _____ year
2. Regularity of cycle Regular ☐ Irregular ☐

3. Length of cycle [Days]

4. Duration of flow [Days]

5. Dysmenorrhoea started at age _____ years

6. Presence of abdominal pain other than around the time of menstruation

1. Yes ☐ 2.No ☐

GYNAECOLOGICAL HISTORY

1. Amount and onset of the discharge_____
2. Colour_____
3. Odour: 1.Yes ☐ 2.No ☐
4. *Consistency*

MEDICAL/SURGICAL HISTORY

Diabetes mellitus: 1.Yes ☐ 2.No ☐

Bacterial vaginosis/vulvovaginal candidiasis: 1.Yes ☐ 2.No ☐

STD (syphilis, HIV, gonorrhoea):1.Yes ☐ 2.No ☐

Malignancy 1. Yes ☐ 2.No ☐

FAMILY HISTORY

Whether this problem runs in family? 1. Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s)

1._____

2._____

3._____

DIETARY STYLE

1.Pure vegetarian ☐ 2.Non-vegetarian ☐

BOWEL HABITS & MICTURITION:

Historyof habitual constipation 1.Yes ☐ 2.No ☐

History of frequent diarrhoea 1.Yes ☐ 2.No ☐

History of frequent dysuria 1.Yes ☐ 2.No ☐

7. **THEGI: [TYPE OF BODY CONSTITUTION]**

Vatham predominant		Kabam predominant	
Pitham predominant		Thondha udal	

8. NILAM: [LAND WHERE PATIENT LIVED MOST]

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Palai ☐

(Hillyterrain) (Forest) (Plains) (Coastalbelt) (Aridregions)

9.**KAALAM:[SEASON]**

Kaarkalam ☐ Pinpanikalam ☐

Koothirkalam ☐ Ilavenil ☐

Munpanikalam ☐ Muthuvenil ☐

10. GUNAM:[CHARACTER]

Sathuvam ☐ Rasatham ☐ Thamasam ☐

DAY OF ASSESSMENT :

0^{th} day ☐ 9^{th}day ☐ 18^{th} ☐ 27^{th} day ☐

SIDDHA SYSTEM OF EXAMINATION:

1. ENVAGAI THERVU: [EIGHT-FOLD EXAMINATION]

I.NAADI: [PULSE PERCEPTION]

	0^{th} day	**9^{th} day**	**18^{th} day**	**27^{th} day**
Date				
Vali				
Azhal				
Iyyam				
Vali Azhal				
Azhal vali				
Iyya vali				
Vali Iyyam				
Azhal Iyyam				
Iyya Azhal				

II.NAA:[TONGUE]

	0^{th} day	9^{th} day	18^{th} day	27^{th} day
Date				
Colour	normal/ Red pale/yellow	normal/ Red pale/yellow	normal/ Red pale/yellow	normal/ Red pale/yellow
Taste	Sweet/Sour/ Pungent/ Bitter/None	Sweet/Sour/ Pungent/ Bitter/None	Sweet/Sour/ Pungent/ Bitter/None	Sweet/Sour/ Pungent/ Bitter/None
Coating	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Fissure	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Saliva	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased
Dryness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Glossitis	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Baldness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

III.NIRAM: [COMPLEXION]

0th day	**9th day**	**18th day**	**27th day**
Date			
Dark/pale/ Yellow tinted/ whitish brown	Dark/pale/ Yellow tinted/ whitish brown	Dark/pale/ Yellow tinted/ whitish brown	Dark/pale/ Yellow tinted/ whitish brown

IV.MOZHI: [VOICE]

0th day	**9th day**	**18th day**	**27th day**
Date			
Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Low pitched

V.VIZHI: [EYES] (Lower palpebral conjunctiva)

0th day	**9th day**	**18th day**	**27th day**
Date			
normal/Red pale/yellow	Normal/Red pale/yellow	normal/Red pale/yellow	normal/Red pale/yellow

VI. MALAM:[BOWEL HABITS / STOOLS]

	0th day	**9th day**	**18th day**	**27th day**
Date				
Colour	Dark/pale/ yellow/ Red	Dark/pale/ yellow/ Red	Dark/pale/ Yellow/ Red	Dark/pale/ yellow/ Red
Consistency	Solid/ Semisolid /Watery	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery	Solid/ Semisolid/ Watery
stool bulk	Normal/ Reduced	Normal/ Reduced	Normal/ Reduced	Normal/ Reduced
Constipation	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Diaarhoea	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

VII.MOOTHIRAM: [URINE EXAMINATION]

Neerkkuri	**0th day**	**9th day**	**18th day**	**27th day**
Date				
Niram[Colour]	Yellow/ Red/ White/ Straw coloured/ Crystal clear	Yellow/ Red/ White/ Straw coloured/ Crystal clear	Yellow/ Red/ White/ Straw coloured/ Crystal clear	Yellow/ Red/ White/ Straw coloured/ Crystal clear

Manam[Odour]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Nurai[Froth]	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased
Edai[Sp.gravit]	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced
Enjal[Deposits]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Volume	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced

Neikkuri	**0th day**	**9th day**	**18th day**	**27th day**
Date				
Serpentine fashion	at___mints	at___ mints	at___ mints	at___ mints
Annular/Ringed fashion	at___mints	at___ mints	at___ mints	at___ mints
Pearl beaded fashion	at___mints	at___ mints	at___ mints	at___ mints
Mixed fashion	at___mints	at___ mints	at___ mints	at___ mints
Other fashion	at___mints	at___ mints	at___ mints	at___ mints

VIII. SPARISAM: [PALPATORY PERCEPTION]

0th day	**9th day**	**18th day**	**27th day**
Date			
Warmth/Hot/ cold/ Sweat	Warmth/Hot/cold/ Sweat	Warmth/Hot /cold/ Sweat	Warmth/Hot/ cold/ Sweat

2. IYMPORIGAL:[SENSORY ORGANS]

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Mei [Skin]				
Vaai[Buccal cavity]				
Kan [Eyes]				
Mooku[Nose]				
Sevi [ear]				

3. IYMPULANGAL: [MOTOR ORGANS]

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Kai [upperlimb]				
Kal [lowerlimb]				
Vai[Buccal cavity]				
Eruvai [excretory organ]				
Karuvai[Reporduc-tive organ]				

4. KOSAM: [SHEATHS]

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Annamaya kosam				
PranamayaKosam				
Manonmayakosam				
Vingyanamaya kosam				
Anandhamaya kosam				

5. MUKKUTRAM: [AFFECTION OF THREE HUMORS

A) VATHAM:

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Praanan				
Abaanan				
Samaanan				
Udhaanan				
Viyaanan				
Naahan				
Koorman				
Kirukaran				
Devathathan				
Dhananjeyan				

B) PITHAM:

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Anarpitham				
Prasakam				
Ranjakam				
Aalosakam				
Saathakam				

C) KABAM:

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Avalambagam				
Kilethagam				
Pothagam				
Tharpagam				
Santhigam				

6. SEVEN DHATHUS: [SEVEN SOMATIC COMPONENTS]

	0th day	**9th day**	**18th day**	**27th day**
Date				
	Normal/ Affected	**Normal/ Affected**	**Normal/ Affected**	**Normal/ Affected**
Saaram[chyme]				
Senneer[Blood]				
Oon[Muscle]				
Kozhuppu[Fat]				
Enbu[Bones]				
Moolai[Bone marrow]				
Sukkilam/Suronitham [Genital discharges]				

7. SYSTEMIC EXAMINATION:

	0th day	**9th day**	**18th day**	**27th day**
Date				
CardioVascular System				
Respiratory System				
Gastrointestinal System				
Genit urinary system				

8. GENERAL EXAMINATION:

	0th day	**9th day**	**18th day**	**27th day**
Date				
Height (cms)				
Weight (kg)				
Temperature(°F)				
Pulse rate (per min)				
Heart rate (permin)				
Respiratory rate(per min)				
Blood pressure(mm/Hg)				
Pallor				
Jaundice				
Cyanosis				
Lymphadenopathy				
Pedal edema				
Clubbing				
Jugular vein pulsation				

9. CLINICAL SYMPTOMS:

	0th day	**9th day**	**18th day**	**27th day**
Date				
Profuse, thin, creamy, whitish/yellowish discharge				
Purities vulva				
Vulval irritation				
Dysuria				

Abdominal pain				
Low backache				
Dyspareunia				

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSSPANDITHARHOSPITAL
DEPARTMENT OF MARUTHUVAM

Clinical Evaluation of Siddha drug "MEGA RAJANGA KIRUTHAM" (Internal)

"VELLAI NOI (LEUCORRHOEA)"

FORM III LABORATORY INVESTIGATION FORM

1. OP/IP No: _____ 2 .S. No: _____ 3.Reg no:

BLOOD INVESTIGATION		**Before treatment Date:**	**After treatment Date:**	**NORMAL VALUES**
HB (gms %)				11-15
T.RBC(milli/cu.mm)				3.5-5.5
ESR (mm)	½ hr.			2-6
	1 hr.			4-8
T.WBC (cu.mm)				4000-11,000
DIFFERENTIAL COUNT (%)	Polymorphs			40-75
	Lymphocytes			20-35
	Monocytes			2-10
	Eosinophils			1-6
	Basophils			0-1
Blood glucose (mg/dl)	Fasting			80-120
	PP			<130
	Random			<140
Lipid profile (mg/dl)	Serum cholesterol			150-250
	HDL			30-60
	LDL			Upto 130
	VLDL			40
	TGL			Upto 160
RFT (mg/dl)	Blood urea			16-50
	Serum creatinine			0.6-1.2
	Serum Uric acid			2.5-7.5
LFT (mg/dl)	Total bilirubin			0.2-1.2
	Direct bilirubin			0.1-1.2
	Indirect bilirubin			0.2-0.7
	Serum total protein			6-8
	Serum Albumin			3.5-5.5
	Serum globulin			2-3.5
	Serum fibrinogen			

	Serum calcium			9-11
	Serum phosphorous			2-5
	SGOT IU/L			0-40
	SGPT IU/L			0-35
	Alkaline phosphatase IU/L			80-290

URINE INVESTIGATION

Urine investigation	**Before TMT(with Date)**	**After TMT (With Date)**
Albumin		
Fasting sugar		
PP sugar		
Random Sugar		
Deposits		
Bile salts		
Bile pigments		
Urobilinogen		

MICROBIOLOGY

SEROLOGY	**Before treatment Date:**	**After treatment Date:**
VDRL		

SPECIAL INVESTIGATION

WET TEST FOR TRICHOMONAS VAGINALIS	**Before treatment Date:**	**After treatment Date:**

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDOSS PANDITHAR HOSPITAL

DEPARTMENT OF MARUTHUVAM

Clinical Evaluation of Siddha drug "MEGA RAJANGA KIRUTHAM" (Internal) in "VELLAI NOI (LEUCORRHOEA)"

FORM IV -DRUG COMPLIANCE FORM

S. NO: --------- OPD/IPD NO: ---------- NAME: ---------- REG NO:

Name Of The Drug: Mega rajanga kirutham-4 ml bid before food

DAY	DATE	MORNING	EVENING
DAY1			
DAY2			
DAY3			
DAY4			
DAY5			
DAY6			
DAY7			
DAY8			
DAY9			
DAY 10-18	DRUG	HOLIDAY	
DAY19			
DAY20			
DAY21			
DAY22			
DAY23			
DAY24			
DAY25			
DAY26			
DAY27			

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDASS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM
Clinical Evaluation of Siddha drug "MEGA RAJANGA KIRUTHAM" (Internal) in

"VELLAI NOI (LEUCORRHOE)"

FORM V- PATIENT INFORMATION SHEET

Name of the Principal Investigator: Dr.S.SANTHANA KITTU (PG Student)
Name of the Institution : National Institute of siddha, TambaramSanatorium

Chennai-47.

I **Dr.S.Santhana kittu** studying M.D (Siddha) in National Institute of Siddha, Chennai. I am doing a clinical trial on the study of Vellai noi (Leucorrhoea due to Trichomonas vaginalis).It is the most common easily curable Sexually transmitted disease. The factors like increasing age,illiteracy,low socioeconomic status,high parity,induced abortion & place of delivery are all contributing factors for occurrence of vaginal discharge.It includes symptoms of Profuse, thin, creamy whitish/yellowish discharge ,Vulval irritation,Pruritis vulva,Dysuria,Abdominal pain,Low backache,Dyspareunia.This condition is being treated in NIS with many siddha formulations. As a part of M.D(S) research programme and developing new efficacious medicine, I have proposed to study the drug Mega rajanga kirutham for treating this condition. This formulation has been mentioned in siddha literature and empirical evidence with contemporary tools is required for documentation. You can receive medicines free of cost. The duration of treatment period is 27 days. You have to visit NIS 9 days once and collect drugs for 9days. The diagnosis tests will be carried out free of cost .We will assess the effect of treatment after completion of 27days of treatment using clinical and lab parameters.

In this regard, I need to ask you few questions. I will maintain confidentiality of your comments and data obtained from you. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study.

Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study. You can choose not to answer any specific question. There is no specific benefit for you if you take part in the study, but you will be under our clinical monitoring and specific attention will be given for your health. Taking part in the study may be of benefit to the community, as it may help us to develop medicine for Vellai noi. In case of any adverse symptoms like severe low back pain, increased profuse white discharge during the treatment shall be reported to me and care will be taken in NIS for relief. You can withdraw from the study at the midst of treatment period, if you are not interested to continue and you will receive our usual treatment without condition.

The information collected in this study, will remain between you and me as a principal investigator. I will not write your name on different forms which sent to different investigating/analysis sections and I will use a code instead given by the principal investigator. Only the principal investigator will know the key to this code which will be kept in safe custody. If you agree to be a participant in this study, you will be screened as per the study protocol.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr,Santhana kittu, PG student cum principal investigator of this study, attached to the National Institute of Siddha, Chennai (Mobile phone no:**9952410979**). You can also contact the Chairman/Member-secretary of Ethics committee, National Institute of Siddha, Chennai – 600047, Tel no: 91-44-22411611, for rights and participation in the study.

தேசிய சித்த மருத்துவ நிறுவனம், சென்னை 47
அயோத்திதாசர் பண்டிதர் மருத்துவமனை
வெள்ளை நோய்க்கான சித்த மருந்தின் (மேகராஜாங்க கிருதம்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

FORM V- தகவல் படிவம்

முதன்மை ஆராய்ச்சியாளர் பெயர் : Dr. சி.சந்தனகிட்டு
நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
தாம்பரம் சானட்டோரியம்
சென்னை 47

Dr. சி.சந்தனகிட்டு. ஆகிய நான் தேசிய சித்த மருத்துவமனையில் பட்ட மேற்படிப்பு பயின்று வருகிறேன். வெள்ளை நோய் என்னும் நோயாகும் எளிதில் குணப்படுத்தக்கூடிய ஒரு பால்வினை நோயாகும். இந்நோயானது அதிகபடியான வெள்ளை கசிவு,பிறப்புறுப்பில் அரிப்பு,சிறுநீர் எரிச்சல்,முதுகு வலி, புணர்ச்சி வலி போன்ற குறிகுணங்களைத் தோற்றுவிக்கும். இந்நோய்க்கு தேசிய சித்த மருத்துவமனையில் பல சித்த மருந்துகள் பயன்படுத்தப்பட்டு வருகின்றது. சித்த மருத்துவ பட்ட மேற்படிப்பில், ஆய்வின் ஒரு பகுதியாக புதிய மருந்துகளை பயன்படுத்தும் நோக்கில்(மேகராஜாங்க கிருதம்) என்னும் மருந்தினை இந்நோய்க்கு வழங்க பரிந்துரை செய்கிறோம். இந்த மருந்தின் செய்முறை, அளவு, அனுபானம் மற்றும் மருத்துவ பயன்கள் அனைத்தும் அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது. எந்தவித கட்டணமுமின்றி தாங்கள் இந்த மருந்தினை பெற்றுக்கொள்ளலாம். இந்த ஆய்வில் மருந்து உட்கொள்ளும் காலம் 27 நாட்கள் ஆகும். 9 நாள்களுக்கு ஒருமுறை தேசிய சித்த மருத்துவமனைக்கு நேரில் வந்து மருந்தினை பெற்றுக்கொள்ள வேண்டும். இந்த ஆய்வு சம்பந்தமான ஆய்வக பரிசோதனைகள் கட்டணமின்றி செய்யப்படும். 27 நாட்கள் மருந்து உட்கொள்ளும் காலம் முடிந்த பிறகு நோய்க்கான குறிகுணங்கள் மற்றும் ஆய்வக பரிசோதனைகள் இவற்றின் முடிவுகளின் அடிப்படையில் மருந்தின் பரிகரிப்புத்திறன் கண்டறியப்படும்.

இந்த ஆய்வு சம்பந்தமாக சில கேள்விகளை தங்களிடம் கேட்க இருக்கிறேன். தங்களிடமிருந்து பெறப்படும் கருத்துக்கள் மற்றும் குறிப்புகள் அனைத்தும் நம்பிக்கையாக பதிவு செய்யப்படும்.இந்த ஆய்வில் தங்களை உட்படுத்திக்கொள்வதின் மூலம் எந்த வகையிலும் பாதிப்புக்குள்ளாக மாட்டீர்கள் என உறுதி அளிக்கிறேன்.

எந்தவித வற்புறுத்தலுமின்றி, இந்த ஆய்வில் பங்கேற்கவும், இந்த ஆய்வு சம்பந்தமாக கேட்கப்படும் கேள்விகளுக்கு பதில் கூறவும் தங்களுக்கு முழு சுதந்திரம் அளிக்கப்படுகிறது.

இந்த ஆய்வில் பங்கேற்பதற்கு எந்த சன்மானமும் வழங்கப்படமாட்டாது. ஆனால், ஆய்வு முழுவதும் எனது மேற்பார்வையிலும், தங்கள் உடல்நலன் குறித்த தனி கவனத்திலும் ஆய்வு மேற்கொள்ளப்படும். வெள்ளை நோய்க்கான புதிய மருந்தின் பரிகரிப்புத்திறனை சமூகத்திற்கு உணர்த்தும் வகையில் இந்த ஆய்வு மேற்கொள்ளப்படுகிறது. இந்த ஆய்வில், மருந்து உட்கொள்ளும் காலத்தில் சிலருக்கு மிக
அதிகபடியான வெள்ளை கசிவு , தாங்கமுடியாத முதுகுவலி போன்ற மாறுபட்ட குறிகுணங்கள் தொடர்ந்து இருக்கும் பட்சத்தில், முதன்மை ஆராய்ச்சியாளரான என்னிடம் தெரிவிக்கப்பட்டு, தேசிய சித்த மருத்துவமனையில் அதற்க்கான தீர்வு வழங்கப்படும். இந்த ஆய்வினைத் தொடர தங்களுக்கு விருப்பம் இல்லையெனில், எப்பொழுது வேண்டுமானலும் ஆய்வின் இடையில் விலகிக்கொள்ளவும், இம்மருத்துவமனையில் வழங்கப்படும் இந்நோய்க்கான வழக்கமான மருந்துகளை பெற்றுக்கொள்ளவும் அறிவுறுத்தப்படுகிறீர்கள்.

இந்த ஆய்வில் சேகரிக்கப்படும் விபரங்கள் அனைத்தும் தங்களுக்கும் முதன்மை ஆராய்ச்சியாளரான எனக்கும் இடையில் இரகசியமாக வைக்கப்படும். கேள்வி பதில் வடிவத்தில் தங்களிடம் கேள்விகள் கேட்கப்படும். அனைத்துப் படிவங்களிலும் தங்களின் பெயர் தவிர்க்கப்பட்டு ஆய்வாளரால் தங்களுக்கென தனிக் குறியீடு வழங்கப்படும். அந்தக் குறியீடு ஆய்வாளருக்கு மட்டுமே தெரிந்ததாக இருக்கும். நீங்கள் இந்த ஆய்வில் பங்கேற்க விருப்பப்பட்டால், திட்ட வரைவு படி தேர்வு செய்யப்படுவீர்கள்.

நீங்கள் இந்த ஆய்வில் பங்கேற்கும் முன், இந்த ஆய்வினைப் பற்றிய மேலும் விபரங்கள் பெற வேண்டுமென விருப்பப்பட்டால், இந்த ஆய்வின் முதன்மை ஆராய்ச்சியாளர் மற்றும் தேசிய சித்த மருத்துவமனை, பட்ட மேற்படிப்புத்துறை மாணவி Dr சி.சந்தனகிட்டு ஆகிய என்னை **9952410979** என்ற எண்ணில் தொடர்பு கொள்ளலாம். மேலும், நீங்கள் இந்த ஆய்வில், உங்களது பங்கேற்பு மற்றும் உரிமை பற்றி தெரிந்து கொள்ள தேசிய சித்த மருத்துவமனை, தலைவர்/செயற்க்குழு உறுப்பினர் அவர்களையும் 91-44-22411611 என்ற எண்ணில் தொடர்பு கொள்ளலாம்.

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

Clinical Evaluation of Siddha drug "MEGA RAJANGA KIRUTHAM" (Internal) in VELLAI NOI (LEUCORRHOEA)"

FORM VI –INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness **Left thumb Impression of the Participant**

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை - 47.

பட்ட மேற்படிப்பு மருத்துவத்துறை

வெள்ளை நோய்க்கான சித்த மருந்தின் (மேகராஜாங்க கிருதம்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்

FORM VI- ஒப்புதல் படிவம்

நான் மேற்கூறிய தகவல் படிவத்தை படித்து அல்லது படிக்க கேட்டு கொண்டேன். - து தொடர்பான விளக்கங்களையும் கேட்டு தெரிந்து கொண்டேன். எந்த வித வற்புறுத்தலின்றி, என் சொந்த விருப்பத்தின் பேரில் என்னை - ந்த ஆராய்ச்சிக்கு உட்படுத்த என் முழுமனதோடும் சுயநினைவோடும் சம்மதம் தெரிவிக்கின்றேன். எனக்கு விருப்பமில்லாத பட்சத்தில் இந்த ஆராய்ச்சியில் இருந்து என்னை எப்போது வேண்டுமானாலும் விடுவித்து கொள்ளும் உரிமையை பெற்றுள்ளேன் என்பதையும் அறிவேன்.

தேதி:

இடம்:

சாட்சிக்காரர் கையொப்பம்:

பெயர்:

கையொப்பம்:

உறவுமுறை :

பெயர் :

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
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Clinical Evaluation of Siddha drug "MEGA RAJANGA KIRUTHAM" (Internal) in "VELLAI NOI (LEUCORRHOEA)"

FORM VII-WITHDRAWAL FORM

1. SERIAL NO OF THE CASE: ……

2. OP / IP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

6. DATE OF TRIAL COMMENCEMENT: ……...

7. DATE OF WITHDRAWAL FROM TRIAL: ……..

8. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD:**

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Please note: i. All consumers / patients and reporters information will remain confidential.
ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: State:

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

<table>
<tr><td>Name</td><td>Father name</td><td rowspan="2">Patient / Record No.</td></tr>
<tr><td>Ethnicity</td><td>Occupation</td></tr>
<tr><td colspan="2" rowspan="2">Address
Village / Town
Post / Via
District / State</td><td>Date of Birth / Age:</td></tr>
<tr><td>Sex: Male / Female
Weight :
Degum:</td></tr>
</table>

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation		**Season:**
Description of reaction		**Geographical area:**

3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

Medicine	Daily dose	Route of administration & Vehicle - Adjuvant	Date		Diagnosis for which medicine taken
			Starting	Stopped	
Siddha					
Any other system of medicines					

4. Brief details of the Siddha Medicine which seems to be toxic :

Details	Drug – 1	Drug – 2	Drug – 3
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			
c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

5. Treatment provided for adverse reaction:

6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

<table>
<tr><td>Recovered:</td><td>Not recovered:</td><td>Unknown:</td><td>Fatal:</td><td>If Fatal

Date of death:</td></tr>
<tr><td rowspan="2">Severe: Yes / No.</td><td colspan="4">Reaction abated after drug stopped or dose reduced:</td></tr>
<tr><td colspan="4">Reaction reappeared after re introduction:</td></tr>
</table>

Was the patient admitted to hospital? If yes, give name and address of hospital	

7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

8. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others

9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / **Distributor / Supplier / Any others (please specify)**
Name:
Address:
Telephone / E – mail if any :

Signature of the reporter: Date:

Please send the completed form to:

Name & address of the RRC-ASU / PPC-ASU

The Director

National Institute of Siddha,

(Pharmacovigilance Regional Centre For Siddha Medicine),

Tambaram Sanatorium, Chennai-600 047.

☏ (O) 044-22381314 Fax : 044 – 22381314

Website : www.nischennai.org

Email: nischennaisiddha@yahoo.co.in

* ** * * * *

This filled-in ADR report may be sent within one month of observation /occurrence of ADR

Who Can Report?

⇒ Any Health care professionals like Siddha Doctors / Nurses / Siddha Pharmacists / Patients etc.

What to Report?

⇒ All reactions, Drug interactions,

Confidentiality

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent.

⇒ Submission of report will be taken up for remedial measures only not for legal claim

Signature of the Investigator:

Signature of the Lecturer:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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